VOLUME 7 NUMBER 2

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Food-Drug-Cosmetic Law Journal

FEBRUARY • 1952

The Food and Drug Administration's Viewpoint on Chemicals in Food . .
C. W. CRAWFORD

Pesticidal Residues on Natural Foods .
L. G. COX

Chemicals in Foods Legislation . . . .
FRED BARTENSTEIN, JR.

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A COMMERCE CLEARING HOUSE PUBLICATION
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The editorial policy of the monthly FOOD DRUG COSMETIC LAW JOURNAL is to record the progress of this law and to provide a constructive discussion of it, according to the highest professional standards. The JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need.

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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

About the Authors

Commissioner **C. W. Crawford** presents the Food and Drug Administration's views on the chemicals-in-foods question in this issue of the JOURNAL. His article is derived from an address delivered before the Inter-Industry Conference on Chemicals in Foods sponsored by the Manufacturing Chemists' Association last month. Mr. Crawford has been with the FDA for more than 34 years, succeeding Dr. Paul B. Dunbar as Commissioner last June 1.

Dr. **L. G. Cox** examines the problem of controlling pesticidal residues on raw materials going into baby foods, and how the problem can be solved. The published material is his testimony given when he appeared before the House Select Committee to Investigate the Use of Chemicals in Food Products on January 31. Dr. Cox is in charge of special technical projects for the Beech-Nut Packing Company, manufacturer of baby foods, peanut butter, coffee and chewing gum. The company is situated in Canajoharie, New York.

At the meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association, held at New York City on January 23, **Fred Bartenstein, Jr.,** discussed chemicals-in-food legislation. Long-time JOURNAL readers will recall Mr. Bartenstein as a contributor during 1948. He is counsel for Merck & Company, Inc., Rahway, New Jersey.

A vice president of Swift & Company, in charge of research, **R. C. Newton** is prominently active in many scientific organizations. These include the American Chemical Society, the American Institute of Chemical Engineers, the Institute of Food Technologists, the Industrial Research Institute, the American Oil Chemists' Society, Sigma Xi and the American Association for the Advancement of Science. In connection with the American Chemical Society, Dr. Newton is past chairman of the Division of Agricultural and Food Chemistry, and for ten years was a member of the board of directors of the Chicago section—during one term, chairman.

Frank L. Gunderson is Research and Development Vice President, Pillsbury Mills, Inc., Minneapolis. He joined Pillsbury in October, 1945, after serving in Washington, D. C., for three and one-half years with the National Research Council. He had been executive secretary of the council's food and nutrition board, which functioned as an advisory body on scientific matters concerning food and nutrition, particularly to the Quartermaster Corps and Surgeon General's Office of the War Department, the Bureau of Medicine and Surgery of the Navy, and the Department of Agriculture, as well as to other federal offices. Prior to his service in Washington, Dr. Gunderson for 12 years was biochemist in charge of nutrition work with The Quaker Oats Company in Chicago, and before that for six years had been assistant chemist in the state regulatory laboratory in Wisconsin.

F. N. Peters, Jr., of Evanston, Illinois, is Vice President, Chemical Research, of The Quaker Oats Company. His first job with Quaker was as a research chemist on a supported fellowship. Since that time he has been employed by the company as a chemical salesman, as manager of the technical division, as director of research and in his present capacity, in which he has been engaged since 1946. Dr. Peters is a member of the Institute of Food Technologists, the American Chemical Society, the American Association for the Advancement of Science, the American Association of Cereal Chemists, Sigma Xi, Alpha Chi Sigma and Gamma Alpha.

Mr. Peters, who was born in Kansas City, Missouri, holds degrees from the Universities of Missouri and Wisconsin.

His accomplishments far outdistancing his years, **Marx Leva** is a graduate of the University of Alabama, where he received the degree of Bachelor of Science in 1937. He was graduated from Harvard Law School in 1940, then served as law clerk to Justice Hugo Black of the United States Supreme Court until 1941, when he was appointed senior attorney in the Office of the General Counsel of the War Production Board. In 1942 he served as acting regional attorney for WPB for Michigan and Northern Ohio. He reported for active duty with the Navy in October of that year. On February 1, 1946, Mr. Leva was released to inactive duty.

He was subsequently appointed counsel to the Fiscal Director of the Navy. In 1947, he became special assistant and personal counsel to Secretary of the Navy James Forrestal. When Secretary Forrestal became Secretary of Defense, Marx Leva was appointed his special assistant. In addition, Mr. Leva served from 1947 to 1949 as general counsel of the National Military Establishment. He was sworn into office as Assistant Secretary of Defense on September 12, 1949, and held that position until he resigned effective May 1, 1951. He now practices law in Washington, D. C. In January of 1950, Mr. Leva was selected by the Junior Chamber of Commerce of Washington as its 1949 choice for "the outstanding young man in government service."

J. Philip Smith, a native New Yorker, received his Bachelor of Laws degree from St. John's University, Brooklyn, in 1944. Upon admission to the New York bar that year, Mr. Smith joined the legal staff of Charles Pfizer & Company, Inc. He is a member of the New York County Lawyers Association, Phi Delta Phi legal fraternity and the Manufacturing Chemists' Association Committee on Chemicals in Foods.

G. J. Williams, of Midland, Michigan, received his B. A. degree from Williams College, Williamstown, Massachusetts, in 1942. He entered the Army Air Force in 1942 and, upon separation from the service in 1945, went on to the University of Michigan Law School, and was graduated with the degree of Doctor of Jurisprudence in 1948. He began work in the legal department of The Dow Chemical Company in March of that year. His employment with Dow includes matters relating to the Federal Food, Drug, and Cosmetic Act; the Federal Insecticide, Fungicide, and Rodenticide Act; and many state laws dealing with the same subjects.

Author of the closing article of the February issue is **George P. Larrick,** Deputy Commissioner of Food and Drugs, Federal Security Agency. Mr. Larrick, who has been associated with the FDA for almost 30 years, has come up through the ranks from his first position as a food and drug inspector to his present status as second in rank to Commissioner Crawford. Mr. Larrick has been a frequent and authoritative writer of articles for the JOURNAL since its beginning in 1946.

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Food·Drug·Cosmetic Law
Journal

THE FOOD AND DRUG ADMINISTRATION'S VIEWPOINT ON

CHEMICALS IN FOOD

By C. W. CRAWFORD
Commissioner of Food and Drugs

This Paper Was Presented Before the Inter-Industry Conference on Chemicals in Foods, Sponsored by the Manufacturing Chemists' Association, Inc., and Held in New York City, January 15, 1952

I AM GRATEFUL for the opportunity to present the views of the Food and Drug Administration to this conference on chemicals in foods. I am sure we all agree that the law must protect the public health against danger from the use of toxic or deleterious substances in food. I am also sure that we would find wide areas of agreement on the many things that legislation on this problem should contain or should not contain, if we fully understood each other's viewpoints. Most of the differences obviously arise from misunderstandings that ought not to exist. For this reason we in the Food and Drug Administration have urged representatives of your association, after the few brief talks we have had with them about the problem, to return for further and more comprehensive discussions. Let me renew that invitation here again.

Much confusion has come from the convenient but inaccurate reference to the problem by the expression "chemicals in food." The ineptness of that expression is apparent when we consider that foods themselves are chemicals, and that the living organism which consumes food is itself a complex of chemicals in which uncounted chemical reactions sustained by food are continuously occurring.

If we are to understand the real problem, its nature and its scope, we must define it more precisely. To use the term "new chemicals in food" does not help much because the real question does not necessarily involve the newness of the chemical. Nor would it help much to define it as "dangerous chemicals in food." That expression covers too much territory. Where the nature and extent of the danger from the use of a chemical in food is known, existing law deals with it effectively.

To appraise the need for new legislation on chemicals in food we should consider just what provisions relating to this question are in the law now. From the text of the Federal Food, Drug, and Cosmetic Act we see that it defines any food as adulterated (1) if it contains a poisonous or deleterious substance which may render it injurious to health or (2) if it contains any such substance that is not required in the production of the food or that can be avoided by good manufacturing practice or (3) where it is so required or cannot be so avoided, if it exceeds the tolerance prescribed by the Federal Security Administrator after public hearing.

In prescribing a tolerance the law directs the Administrator to take into account the extent to which the poisonous or deleterious substance is required or cannot be avoided in the production of each food, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances. In every event the Administrator is enjoined to prescribe the tolerances at such levels that the public health will be protected.

Reading the statute impresses one with the clear intent of Congress to go further than merely insuring that no single food will itself carry enough poison to jeopardize the health of the consumer. The purpose was to safeguard the Nation's food supply so that the over-all quantity of toxic substances, in all the items that make up the varied diet characteristic of American people, will be held at safe levels.

The language chosen to prevent the unnecessary addition of poisonous or deleterious substances is worthy of careful study. Traffic in food containing such a substance, in any quantity whatever, is prohibited "except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice." While the meaning of the word "required" has not yet been interpreted by appellate courts, it seems fair to assume that a real or fancied improvement or advantage resulting from an added poison would not be

enough; that to satisfy the law the added substance actually must be essential to production. It appears that Congress regarded the addition of poisons to our food supply as too hazardous to permit except in the face of real necessity.

Some further light on the intent of Congress is shed by committee reports on the bill which became the present law. The following is a quotation:

> "In promulgating such regulations [prescribing tolerances] this section requires that there be taken into account the extent to which the use of the poison is required in the production of the article, as for example, poisonous sprays in producing certain fruits and vegetables, and likewise, the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances. This authorization will permit the establishment of comparatively liberal tolerances for any food where poison is unavoidable or is required by the necessities of production, and less liberal tolerances or complete prohibitions where it is practicable to limit the amount of poison in a particular food to very small quantities, or to eliminate it completely. It will likewise afford adequate control of those situations where irresponsible manufacturers, for some fancied or real commercial advantage, add dangerously toxic substances to foods . . . ."

The purpose of Congress to exclude from the Nation's food supply poisonous or deleterious substances, in whatever quantity, unless those substances are actually required in producing that food, should be kept clearly in mind in considering the problem of chemicals in food.

Specific Provisions of Law

Let us turn now from the general policy and pattern of the law to a study of its specific provisions. A food is defined as adulterated, first, "if it bears or contains any poisonous or deleterious substance which may render it injurious to health," and, second, "if it bears or contains any added poisonous or added deleterious substance . . . except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice." An essential element of proof common to both these provisions is that the substance in issue is in fact poisonous or deleterious. Unless that fact is known the law does not operate; surmise that it might be poisonous is not enough.

A third provision defines a food as adulterated "if it bears or contains any added poisonous or added deleterious substance . . . required in the production thereof" in "any quantity exceeding the limits fixed" in regulations prescribing tolerances for the protection of the public health. Of course no limit on the quantity of the substance

can be fixed for this purpose without knowledge of just how toxic it is and within what specific limits it is safe.

If this knowledge does not exist and no tolerance can be established, we might consider action under the provision we discussed a few moments ago against any food containing a poisonous or deleterious substance which may render the food injurious to health. Here we run into the second element of proof required by this provision—proof that the quantity of the substance present is such as may render that food injurious to health. Unless the substance has been sufficiently tested to give a clear picture of the degree of its toxicity, there is bound to be a gap of uncertainty within which the quantity of the substance may fall and where no legal action can be taken, notwithstanding the fact that no one knows whether the food is injurious or not. The zone of uncertainty is widened when the substance is used, as has been done, before quantitative methods for its determination in the food have been worked out.

Clarification of Question

With this background on existing law let us try to define the question before this conference. Certainly the terms "chemicals in foods," "new chemicals in foods" and "dangerous chemicals in food" all lack much in precision. It seems to us that the real question is on the use in food of any substance of whatever nature, whether in lay parlance it is a chemical or not, whether it is new or not, when that substance has not been adequately tested, either through human experience or by all reasonably applicable laboratory and clinical procedures, to show either that it is not poisonous or deleterious or, if it is and it is required in the production of a food, that it can be safely used.

This is the relatively narrow but highly important area in which we believe that neither the Federal Food, Drug, and Cosmetic Act nor any other law affords adequate protection to the public health.

It would be both unfair and incorrect to appraise this problem on the assumption that we have an irresponsible chemical industry and an irresponsible food industry, both callous to the health of consumers. Nor can we appraise it on the assumption that this is just a bureaucratic grab for dictatorial powers over the food and chemical industries. The facts belie both assumptions. But the facts show that there is a fringe of the careless or ignorant or unscrupulous who have used or are now using chemicals in food without sufficient testing to be

reasonably certain they will not impair the health of consumers. We have seen insecticides marketed before toxicity tests were made, other than those required to show the LD_{50}, and before adequate quantitative analytical methods were developed. We have seen the paradox of vigorously pressed sales campaigns for chemical additives while tests to discover unknown facts about their toxicity were being planned or carried out.

That the dramatic equivalent of the elixir sulfanilamide disaster of 1937 that cost more than a hundred lives has not occurred in the food field speaks volumes, first, for the conscientiousness of these industries generally and, second, for the providential luck of the fringe operators—and of the public. We have had some narrow escapes.

Much has been said about the impossibility of guaranteeing the absolute safety of any food additive for all people under all circumstances, and about the toxicity of nearly every common food to hypersensitive individuals. The point is well taken. But this does not mean that nothing should be done toward setting up legal safeguards to minimize other and more avoidable dangers. A practical, commonsense solution can be worked out if the nature and scope of the problem are clearly recognized and if a constructive approach is followed.

Leaders in the food and chemical industries have set some practical guidelines. In their investigations of the prospective use in food of chemicals of unknown safety they have used every reasonably applicable test. Each point on which the chemical might be suspect is thoroughly explored. It is not until every reasonable check has been made, all with negative results, that the chemical is put into use. This procedure is not only highly desirable; it is highly expensive. We believe that what is being voluntarily done by the majority should be required of those who are less conscientious and who may prematurely launch competitive products at the risk of consumer health and to the detriment of returns from properly tested products. An amendment to accomplish this objective need not disturb the present majority practice, or any provision or procedure of existing law.

Little Protection in Suggested Amendment

The objective would not be accomplished by the suggested amendment to provide that the Food and Drug Administration be notified of the intent to add to any food an ingredient that has not previously been used in that food. Mere notification requires no prior testing; and

testing takes time, no matter whether it is done by the sponsor of the chemical, the Food and Drug Administration or anyone else. Such an amendment would be practically valueless in preventing the use of chemicals of unknown toxicity and in protecting consumers from being used as guinea pigs.

Much criticism has been directed at the amendment proposed in the Miller Bill, H. R. 3257. I must accept personally all blame for any imperfections of that bill. I drafted it, rather hurriedly, at the request of the Delaney Committee, of which Representative Miller is a member. In presenting it to the committee I emphasized the fact that it was purely tentative and that it could be improved. It was my hope, and I am sure it was the hope of the committee and of Dr. Miller, that the draft would aid in crystallizing constructive opinion on the problem.

Miller Bill Patterned on New-Drug Section

I used as a general pattern the new-drug section of the law. What classifies a new drug as such is usually the fact that it contains some chemical that is not generally recognized by qualified experts as having been adequately tested for safety. As I saw it, there was no significant difference in the basic problem arising from the use in drugs of chemicals inadequately tested for safety and that from the use in food of chemicals inadequately tested for safety. The differences seemed relatively minor and could be dealt with through changes in draftsmanship.

Let me illustrate how I envisioned the general working of the bill, regardless of the sufficiency of its language. A manufacturer finds that certain kinds or classes of food can be improved by adding a chemical. That chemical is not required in the production of these foods, nor is it generally recognized by qualified experts as having been adequately tested to show that it is not poisonous or deleterious.

The manufacturer tests the chemical by all reasonably applicable methods to supply this information. He focuses his study on the chemical itself rather than on foods containing it in quantities he considers using. If he finds that it is poisonous or deleterious—that it causes harm when ingested in any quantity in which it can readily be consumed—he should abandon the project. Public policy as expressed in existing law forbids the unnecessary use of such substances in food.

If he believes the tests show that the chemical is not poisonous or deleterious, he submits all his data with an application to the Federal

Security Administrator for use of the chemical in food. If the Administrator agrees with him, the application is made effective. So far as any provision of the law concerning poisonous or deleterious substances is concerned, the applicant can then use the chemical or sell it for use in food of any kind. Other provisions of the law on adulteration and misbranding would of course have to be observed.

If the Administrator believes the data leave a reasonable doubt as to whether the chemical is poisonous or deleterious, the applicant will be so advised. If he wishes, the applicant can do additional work on the point in question or he can demand a formal hearing before the Administrator, at which a record will be made of all evidence on both sides of the question. If the Administrator is still unconvinced, he issues an order refusing to permit the application to become effective. The applicant can appeal the order to the federal courts, which have power to set it aside if it is unreasonable or arbitrary.

Let us take as a second illustration a chemical which is known to be toxic and which the manufacturer wants to sell for use in destroying predatory insects on one or more food crops or groups of food crops. It is well recognized that the use of some poisonous or deleterious substance is required in producing these crops. The manufacturer tests the chemical by all reasonably applicable methods to determine the degree of its toxicity. He develops quantitative analytical methods for the chemical in or on the foods, unless such methods already exist. He determines the quantities of the chemical remaining in or on the foods, as they are shipped in interstate commerce, when the chemical has been used on the crops at such times and in such quantities as will accomplish its insecticidal purposes.

If he believes the investigation shows that such foods are safe for consumption, he submits his application to the Administrator, accompanied by reports of all his results. He will recite the directions he proposes to use in labeling or otherwise in marketing the article for use on specified food crops or groups of food crops, spraying or dusting schedules and, if necessary, precautions, such as the latest date for safe application before harvest.

If the Administrator agrees with him, his way is cleared to sell the chemical for use under the directions he proposed. Those who buy it and use it in accordance with these directions will be free to market those crops in interstate commerce. If someone uses it in greater quantities, that is the responsibility of whoever does so. Existing provisions

of the law still apply; an authority to provide tolerances can be exercised. If someone wishes to use it for food crops other than those included in the directions, it is the responsibility of that person to submit an application covering such use.

If the Administrator believes that the data submitted by the manufacturer leave a reasonable doubt that the foods will be safe, the procedure for notification, hearing, and court review is the same as that described in the illustration on a chemical that is not required in producing food.

In drafting the Miller bill, an effort was made to fix responsibility for compliance upon the firm or person who sponsors the use of a chemical in food or in circumstances where it is likely to contaminate the food. If the language is not clear in this respect it should be changed to make it so.

No Need for Grandfather Clause

I did not include a so-called grandfather clause in the bill parallel to that in the new drug definition because I did not regard the problem as parallel. This clause excluded from the definition those drugs that had been on the market before the law was passed. In 1938, Congress was enacting two entirely new provisions to guard against dangerous drugs. The first covered any drug that is dangerous to health when used in accordance with directions on its label. The second was the new-drug provision, early drafts of which defined a new drug simply as one not generally recognized by qualified experts as safe for use under the conditions set forth in its labeling. It thus included drugs, then on the market, that were generally recognized as dangerous and that would therefore be subject also to the first provision. Congress decided to limit the new-drug section to drugs that were truly new, and to subject drugs previously on the market to the other provision. To prevent overlapping of the two provisions, Congress modified the definition of a new drug by writing the grandfather clause into it.

In the situation now before us, the law contains adequate provisions on chemicals of known toxicity in foods. We have only one gap to close, rather than the two that were to be closed in the drug law. The gap we now have to close is that through which chemicals of unknown toxicity and potentiality for harm find their way into our foods. To prevent the overlapping of provisions now in the law covering substances of known toxicity, the scope of the proposed amend-

ment was limited to those substances not generally recognized by qualified experts as having been adequately tested. If the public is to be protected from the hazards of inadequately tested substances in food, the time of the beginning of use of such substances, whether before or after enactment of the proposed amendment, is immaterial.

It is not intended to require further testing of any substance that is generally recognized by qualified experts as having been adequately tested. I cannot share the concern expressed that the proposed bill would stop for an indefinite time the use of chlorine in food sanitation or potassium iodide in iodized salt or vitamins and minerals in food enrichment. These are recognized by experts generally as having been adequately tested for safety and, therefore, would not be subject to the proposed amendment.

If doubt exists as to whether experts generally recognize that a chemical now being used has been adequately tested to show its safety, a provision for the amendment to become effective at a specified date after enactment could afford ample time for clearance if the chemical has in fact been adequately tested and is safe. This would safeguard the public, and also the equities of manufacturers who themselves had paid the price of adequate testing. To exempt from the amendment those who had not done so would leave no compulsion for them to shoulder the expense; by doing nothing, they could shift the burden to the government.

Pattern Proven Successful

In approaching the task of draftsmanship the Delaney Committee asked me to do, there were several factors that persuaded me to follow the general pattern set up by the law for new drugs. These provisions have worked smoothly and satisfactorily since 1938, during which time applications have become effective for nearly 6,000 new drugs. Among these are the many so-called wonder drugs which constitute the most spectacular progress in drug therapy of all time.

In one minor case only has litigation arisen over the Administrator's refusal to permit a new-drug application to become effective. This practical absence of litigation has resulted from the fact that, while we have no formally established advisory committee, in every case where a serious question arose we have consulted the outstanding research workers and clinicians in the particular field involved, whoever and wherever they might be.

The problems from the use of drugs inadequately tested for safety and the use in foods of chemicals inadequately tested for safety are fundamentally alike. It seems to me that the time-tested pattern for new drugs should be followed rather than to undertake some new and untried legislative pattern, the effects of which cannot be so clearly foretold.

Enthusiastic Support of New-Drug Protection

The new drug section has been highly effective in protecting the public health. Although the drug industry expressed grave apprehensions about the enactment of that section, they have since become its enthusiastic supporters. Confirmation of this came, shortly before the Miller bill was introduced, in *The Odyssey of Modern Drug Research* by Robert Burlingham, a book published by the Upjohn Company, one of the country's leading drug manufacturers. Let me read some quotations relating to the new-drug section:

> At the time [of enactment] many of the drug manufacturers affected considered the law practically as bad as the medicine that brought it on. (The leading pharmaceutical houses did not take quite so lugubrious a view, since they had argued against the bill on the ground that they already had higher standards of quality and safety control than the law would provide.) Nevertheless, the entire industry settled down to observing the law and the complex regulations issued under the wide enforcement powers granted to the Food and Drug Administration. And in the course of doing so, the manufacturers—some willy, some nilly—found themselves compelled to increase their scientific and technical personnel, to accumulate a vast body of medical evidence on which to launch their products, and in general to apply the principles of rational therapeutics to all their works. . . .
>
> It is to the credit both of the F. D. A. officials and of the drug manufacturers, who have worked in full cooperation to meet the objectives of the law, that the public has been given needed protection from careless or irresponsible drug making, without any hampering of the free enterprise of drug discovery. On the contrary, as already pointed out, the law gave new impetus to pharmaceutical research and new strength to the ties between drug houses and other medical research facilities outside the industry. Although industry and F. D. A. points of view have often differed and sometimes clashed on administrative matters—which, in this case, are almost entirely matters of opinion—a large majority of the industry would certainly be among the first to recommend a head examination for any manufacturer who wanted to repeal the new drug provisions of the law at this late date. . . .
>
> It is true that most of the big-name, full-line houses—houses like Lilly, Upjohn, Squibb, Abbott, and Parke, Davis, for example—had long maintained rigorous manufacturing controls, high quality standards, large-scale pharmacological and clinical testing of new products, and other standards which the new law compelled the whole industry to adopt. But there is no indication that the law has wrought hardship on any company, large or small, except perhaps for its desir-

able discouragement of fly-by-nighters who might otherwise have exploited and possibly endangered the public. On the contrary, the law has profited the whole industry to the extent that the public, including the medical profession, now takes for granted the purity and quality of all drugs on the market and their safety when used in accordance with labeled instructions.

Notwithstanding the reasons I had for adopting the pattern of the new-drug section, I do not wish to discourage consideration of other approaches. Every reasonable proposal should be explored. If someone can come up with a better solution I shall share the gratification everyone concerned will feel.

Of course the Congress will make the final decision. Congress will decide whether an amendment is needed and if so what the amendment shall be. Congressional policy will determine whether the initial decision on the safety of a chemical should be made by the administrative agency, subject to court review for its reasonableness, or as has been proposed, by federal courts and juries.

Legislators will have to weigh the advantages and disadvantages of each of these two ways. They will have to compare the competence of lay courts and juries to resolve these scientific questions from expert testimony presented under the rules of evidence with that of an administrative body having the advice of its own scientific staff and of experts throughout the country. They must consider the degree of nonuniformity to be expected in decisions on similar questions by different courts and juries throughout the country, and the expected uniformity in such decisions from a single continuing tribunal. They must calculate the risk that bureaucratic concepts may influence administrative decisions and weigh that in the balance.

Manufacturing Chemists and Present Problem

The manufacturing chemists of this country have been a powerful and constructive influence in the progress of our Nation and in building its strength. The straight, decisive and courageous thinking that has characterized the industry, its ability to recognize facts in complex confusions with fancy and surmise and theory, can be applied with advantage to the problem before us today. In its solution you can be of great help to the Congress and to the people it represents.

I am wholly confident that the conclusions you reach from your meeting today and the resulting actions you take will be a constructive service for the Nation's welfare. **[The End]**

By L. G. COX

Pesticidal Residues o

PRIOR to the commercial introduction of DDT as an agricultural insecticide, our quality-control program consisted of close bacteriological supervision of equipment, raw materials and finished products; routine insect fragment and mold counts; and chemical analyses for lead, arsenic, fluorine and, occasionally, copper. Periodic checks were made on agricultural raw materials as they arrived at the plant, again at the end of the customary preparation procedures of washing and peeling, and finally on the finished product, in accordance with well-established methods of analysis acceptable both to the National Canners Association and the Food and Drug Administration. In general, a simple wash was sufficient to remove most residues, but on some fruits an acid wash was occasionally required to remove excessive residues of lead and arsenic.

The advent of DDT gave us higher quality fruits and vegetables than we had been able to obtain heretofore. But it also presented a new residue problem with respect to methods of analysis adapted to the minute residues existing on or in food products, methods of economical residue removal, and tolerance standards for residues in the finished product.

Our management immediately made the decision to employ competent chemists in order to develop suitable methods of residue analysis and removal, and gave others of us the responsibility of becoming intimately acquainted with those developments in new pesticides pertinent to our business. This has led to the development of a considerable research program within our own laboratories, supplemented by grants in aid to universities, experiment stations, research institutes, and even the Bureau of Plant Industry of the United States Depart-

ues on Natural Foods

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ment of Agriculture. Our research staff worked closely with the American Medical Association, the Food and Drug Administration, the United States Department of Agriculture, the American Chemical Society, the National Research Council, the National Canners Association, various insecticide manufacturers, trade associations and farm organizations. Eventually we were associated with the formation of the Pesticide Committee of the American Medical Association, the Pesticide Subdivision of the American Chemical Society, and the Food Protection Committee of the National Research Council.

Why Beech-Nut Developed a Policy of Minimum Pesticidal Residues in Foods

Why did we, as early as 1947, deem it necessary to undertake such an extensive and extremely expensive research program on pesticidal residues? Our immediate obligation was to protect the consumer of our products. To do this, we immediately had to develop methods of residue analysis in order to determine whether or not we were providing that protection. Our second obligation was to our stockholders to develop efficient methods of residue removal and an agricultural procurement program which would allow us to operate at a profit. We couldn't take the attitude that all insecticides were harmful, because we needed the production of quality fruits and vegetables at a reasonable price. To achieve this we had to determine which pesticides were effective in use, yet safe for our purposes.

How did we proceed in formulating a procurement procedure and policy which gave us raw materials with minimum residues, and how did we arrive at what we concluded to be a safe residue tolerance in

the finished product? First of all we had to obtain facts, either from the published literature, or from our own research efforts. Let me quickly summarize our basic reasons for arriving at our present operational policies pertaining to DDT and related insecticides:

(1) *Toxicological and related data.*—The insecticide DDT, as well as closely related chlorinated hydrocarbons, has certain properties which, in the absence of good information to the contrary, have forced us to adopt a near zero tolerance level in baby foods. From the published literature, and research programs, which were in progress, the results of which have since been published, we have accumulated certain basic information which led us to this policy. This information may be summarized as follows:

(*a*) A relatively high order of chronic toxicity to which there may be individual variations in susceptibility.

Primary consideration was given to the evidence that young animals are usually more susceptible than older ones and occasionally exhibit marked changes in certain organs, even though body growth may be normal, when subjected to the chronic toxic effects of DDT and related chlorinated hydrocarbons.

Fitzhugh [1] noted the storage of DDT in rats, along with histopathological effects on diets as low as ten ppm, and that 50 ppm diets reduced the number of weanling rats. Later Lehman [2] reported that rats can begin storing DDT at dietary levels below 1 ppm, and accumulate it in body fat in concentrations of 6-28 times that of the original level in the diet. A continued intake of five ppm produces definite but minimal liver damage, and the rate of disappearance of DDT from body tissue is slow.

Radeleff and Bushland,[3] following a series of deaths to young farm animals from commercial treatment by recommended sprays and dips for control of cattle ticks, inaugurated experiments which demonstrated that suckling calves are more susceptible to Benzene Hexachloride, Chlordane and Toxaphene than older animals. More recently,

[1] Fitzhugh, O. G., "Use of DDT Insecticides on Food Products," 40 *Ind. Eng. Chem.* 704-705 (1948).

[2] Lehman, A. J., "Some Toxicological Reasons Why Certain Chemicals May or May Not Be Permitted as Food Additives," 14 *Assoc. Food and Drug Officials U. S. Quarterly Bulletin* 82-98 (1950).

[3] Radeleff, R. D., and Bushland, R. C., "Acute Toxicity of Chlorinated Insecticides Applied to Livestock," USDA Bureau Ent. & Plant Quar. Special Report K-22 (November 9, 1948); Radeleff, R. D., and Bushland, R. C., "Acute Toxicity of Chlorinated Insecticides Applied to Livestock," 43 *Journal Econ. Entomol.* 358-364 (1950).

during the current hearings, Dr. Harris of the Utah Agricultural Experiment Station [4] has said that young turkey poults exhibit a mortality of 31.5 per cent when fed alfalfa hay containing DDT levels of 100 ppm.

With regard to other changes occurring in certain organs at levels of DDT intake at which body growth was apparently normal, Burlington and Lindeman [5] treated white leghorn cockerels, beginning eight days after hatching, with levels of DDT at which body growth was normal, and found that development of the testicles, comb and wattles was greatly inhibited. They suggest that DDT may exert an estrogen-like action similar to certain sex hormones. Likewise, Emmel and Krupe [6] in Germany had previously found that DDT accumulated in lipid-rich organs such as the testicles, thyroid and adrenals.

With respect to laying hens, Rubin, Bird, Green and Carter [7] found that levels of DDT feeding at approximately one-half the lethal dose resulted in reduced egg production and hatchability of the eggs. Along the same line, Tauber and Hughes [8] noted that a diet of 100 ppm of DDT significantly reduced the cholesterol content of the ovaries of female rats, and suggested that cholesterol may be a precursor of progesterone, one of the sex hormones.

The American Medical Association has recently reviewed the pharmacologic and toxicologic aspects of DDT [9] and states:

> Chronic DDT poisoning may result from the ingestion of small amounts of the material over a long time. Since the chemical is irregularly absorbed, the level, below which adverse long range effects are absent, is unknown.

They also give emphasis to the Food and Drug Administration having suggested a tolerance of five ppm as the upper limit on any single item containing DDT residues for human consumption, and less than one ppm if all food is contaminated.

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[4] Harris, L. E., "The Toxicity of DDT and Methoxychlor to Farm Animals and Its Accumulation in Products Consumed by Man," Hearings Before the House Select Committee to Investigate the Use of Chemicals in Food Products, 82d Cong., 1st Sess., Part I, pp. 249-268 (1951).

[5] Burlington, H., and Lindeman, V. F., "Effect of DDT on Testes and Secondary Sex Characters of White Leghorn Cockerels," 74 *Proc. Soc. Exptl. Biol. and Med.* 48-51 (1950).

[6] Emmel, L., and Krupe, M., "The Mode of Action of DDT on Warm-Blooded Animals," 1 *Zeitschr. Naturforsch* (11/12) 691-695 (1946).

[7] Rubin, M., Bird, H. R., Green, N., and Carter, R. H., "Toxicity of DDT to Laying Hens," 26 *Poultry Sci.* 410-413 (1947).

[8] Tauber, O. E., and Hughes, A. B., "Effect of DDT Ingestion on Total Cholesterol Content of Ovaries of White Rats," 72 *Proc. Soc. Exptl. Biol. and Med.* 420-422 (1950).

[9] A. M. A. Council on Pharmacy and Chemistry, "Pharmacologic and Toxicologic Aspects of DDT," 145 *Jour. A. M. A.* 728 (1951).

(*b*) DDT tends to be stored at low levels of dietary intake. There is a tendency for it to accumulate in body fat and certain organs at a higher level than the dietary level, and the subsequent rate of disappearance of DDT from body tissues may be slow.

Since we are manufacturers of baby food, we have had to take into account all those factors (prenatal, environmental, physiological and structural) which may cause a baby to react to food residues in a manner different from the adult.

With regard to prenatal factors, Kinnegan, Haag and Larson [10] reported that both DDT and DDD are stored in the fatty tissues of dogs, and both are transported across the placental barrier to the foetus. More information of this type is badly needed, particularly in humans. With respect to humans we have indirect data that is of interest from Lehman,[11] and Laug, Kunze and Prickett,[12] which indicates that mother's milk in certain areas may already be averaging 0.14 ppm DDT, and human body fat may be averaging 5.1 ppm DDT. The fragmentary data which we have been able to assemble to date indicates, at least, that the new-born baby may already have a slight amount of DDT stored in its tissues, and be receiving additional amounts via its mother's milk prior to the time it is ready for commercial milk or baby food. We are, therefore, of the opinion that any insecticide residue which tends to accumulate in fatty tissue should be eliminated insofar as possible from the baby's diet at the time when milk and prepared baby foods are the major part of its diet.

Young animals certainly possess the ability to accumulate DDT in body fat and other tissues in a manner comparable to older animals. We have occasion to believe that in some cases they may tend to accumulate it to a greater degree. Certainly, in the case of infants where there is a relatively high proportion of body fat as compared with adults, we can take few chances with accumulated residues of DDT or other similar substances suddenly being released by one of many infant disorders, which may cause sudden and appreciable loss of body weight through rapid fat metabolism.

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[10] Kinnegan, J. K., Haag, H. B., and Larson, P. S., "Tissue Distribution and Elimination of DDD and DDT Following Oral Administration to Dogs and Rats," 72 *Proc. Soc. Exptl. Biol. and Med.* 357-360 (1949).

[11] See footnote 2.

[12] Laug, E. P., Kunze, F. M., Prickett, C. S., "Occurrence of DDT in Human Fat and Milk," 3 *A. M. A. Arch. Ind. Hyg. & Occup. Med.* 245 (1951).

Fortunately, we have learned to live with DDT on fruits, at least, through the development of adequate washing or peeling procedures. On potatoes and root crops it presents no problem. On leafy vegetables we do have to avoid the presence of residues at time of harvest, because we have no completely satisfactory method of washing which leaves the vegetable in a condition for further processing. We have also had difficulty with apricots, which, when fully ripe, as we process them, cannot be peeled or given a hot detergent wash. Fortunately, Parathion and other insecticides, whose residues are completely decomposed by harvest time, can be used on this fruit with safety.

(2) *The lack of adequate analytical methods of residue analysis.*—At the present time we have good analytical methods for DDT, DDD, Parathion, Benzene Hexachloride, Methoxychlor and a few other insecticides which are not in general use. Unfortunately, we lack satisfactory analytical methods for Chlordane, Toxaphene, Aldrin, Dieldrin and Heptachlor, all of which are either in general use or show promise of being used on certain crops for which they are badly needed.

Due to our lack of analytical methods, we were obliged to establish an elaborate field-survey program through our agricultural purchasing department, and enforce it by a growers' contract which prohibits the use of certain questionable pesticides. Some time ago, we received field samples of cabbage, which yielded considerable amounts of an unknown residue in one stage of our DDT analysis. A combination of total chlorine analysis, spot tests and infra-red absorption spectra revealed that it was Toxaphene at a level of around 200 ppm.

Because of the Toxaphene and other experiences, we were forced very early to inaugurate a long-term bio-assay project at the Boyce Thompson Institute for Plant Research. The early phases of this program were devoted to the effect of our methods of processing on the breakdown of known amounts of those insecticides which were either being used commercially or which showed promise of being used within the near future. As a result of these studies, we knew that Parathion, BHC, Methoxychlor and a few other insecticides, at levels which normally occurred under good agricultural practice, were largely broken down by processing. DDT and a few others were quite stable, however. In general, the results of this early rough survey were confirmed by subsequent chemical analyses, but we had already been

able to establish our basic purchasing policies. On Parathion alone, we were able to save many thousands of dollars on apricots, at a time when other more stable insecticides were being highly recommended and widely used.

Recently, we have begun to realize that we may be faced with several years of commercial use of certain insecticides, without any hope of developing a chemical method suitable for residue detection on fresh produce, or in the finished product. Toxaphene and Chlordane both fall into this category. We have, therefore, in cooperation with the National Canners Association, continued the Boyce Thompson project with the aim of developing a simple bio-assay method which will be suitable for detecting unknown toxic residues and expressing them in terms of DDT units. We have already found, however, that the limiting factor is a simple and quick method of separating the pesticidal residue from plant fats, waxes and interfering substances in such a way that it can be analyzed by bio-assay. Certain of the miticides apparently cannot be determined by this type of bio-assay. Already this research has paid dividends, for we have found that Chlordane, as a soil residue, contaminates carrots. Thus, we have been able to avoid the purchase of carrots from areas where Chlordane has been used commercially. Note that Lehman [13] says: "It is our opinion that Chlordane has no place in the food industry where ever the remotest opportunity for contamination exists."

We are in the peanut-butter business and, as I will explain later, have encountered considerable difficulty in obtaining peanuts free from BHC contamination. Peanuts are grown in rotation with cotton on which large amounts of BHC are used for insect control. Aldrin and Dieldrin, and perhaps one other insecticide, show promise on both cotton and peanuts. In order to avoid soil contamination from BHC, we are very anxious to see other good cotton and peanut insecticides developed. We already have samples of peanuts from experiments which have exhibited good insect control, but as yet are unable to analyze these nuts satisfactorily, either chemically or biologically, due to interference from excess oil. If we knew that the insecticides used did not constitute a definite hazard, we would do everything possible to encourage their use as a replacement for BHC in the areas where we normally purchase peanuts.

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[13] See footnote 2.

Because of the lack of adequate methods of residue analysis, we are obliged to maintain a policy of refusing to purchase any crops on which insecticides of high chronic toxicity or off-flavor-inducing properties have been used, or which come from soils which have been contaminated by these insecticides. This is a policy which involves a hardship on both ourselves and the farmer, and certainly does not make for good farmer-canner relations, but it has to be done not in our interest or that of the farmer, but in that of the ultimate consumer —the baby, particularly.

(3) *Off flavors.*—(*a*) Benzene Hexachloride. Our first experience with the actual presence of BHC in or on produce came during the 1948 season, when we had to reject 13 out of 89 acres contracted for squash in Florida, peaches from Pennsylvania and celery, also from Florida. We have done considerable testing of spinach from Pennsylvania and have, over the past four years, been forced to reject loads from time to time.

The year 1950 brought to us probably one of the most severe dollars-and-cents losses in handling vegetables exposed to BHC treatment. We were originally contracted in South Carolina for our total requirements of sweet potatoes. By the time we had tested all of the soils on these contracted acreages and had found residues of BHC on a large percentage, we were forced into buying on the open market, in South Carolina, North Carolina and the eastern shore of Maryland at much higher prices. The total financial loss amounted to over $15,000.

Our most recent encounter, as far as rejection of fruits is concerned, dates during the 1951 apple season, when we were forced to reject contracted apples in New York because of BHC contamination.

At our California plant we had to reject dehydrated celery in 1949, because of off odor due to BHC contamination. Later in 1951, we had to reject carrots, because of BHC soil contamination and residues of BHC in the carrots. The same has been true of California sweet potatoes, even on fields where the last official record of BHC use was two years ago. All other sweet potato growers contacted admitted the use of Lindane or BHC, and we had considerable difficulty in obtaining satisfactory lots of sweet potatoes free of BHC for our processing purposes.

Our worst experience with mass contamination of an agricultural crop has been with peanuts from the Southeast, where they are customarily grown in rotation with cotton on which BHC has been used for the control of certain insects. Recently, Poos, Dobbins, Batten and Boush of the USDA have reported off flavors in peanuts and peanut cooking oils from plots treated with various levels of Lindane and Technical BHC.[14] Their data show that peanuts are capable of accumulating considerable amounts of BHC from soils where it had been added, either with or without fertilizer. At rates of application of BHC or Lindane at 1-1.25 pounds per acre, the corresponding values in the nuts ranged from 2-8 ppm. Panel tests at Beltsville, Cornell University, peanut-processing companies, and the USDA Bureau of Human Nutrition and Home Economics, in general, indicated that both raw and roasted peanuts may develop off flavors from both Lindane and BHC under field applications at levels of around one ppm per acre. The quality of oil made from these peanuts has been evaluated for use in French-frying potatoes, and off flavor was noted in the first batch of potatoes fried, but not in later batches.

Our own experience in the Southeast has confirmed that it is quite difficult to obtain peanuts with a BHC content less than 0.5 ppm from certain areas. In fact, during the past year, we have found it difficult to keep up our production, due to the long delay involved in sampling and analyzing various lots of peanuts prior to ultimate purchase. We have been unable to detect off flavor in commercial nuts at levels below 0.5 ppm, a value which is far below any tolerance that is apt to be established by the Food and Drug Administration, due to the low chronic toxicity of BHC. We have preliminary evidence which indicates that peanut butter containing over 2 ppm BHC exhibits some degree of off flavor after a five-month shelf life.

There are certain basic considerations which have forced us to adopt a purchasing policy of rejecting all produce which has been treated, during the formation of edible plant parts, with BHC or Lindane, or which has been grown on soils contaminated by BHC or Lindane. These may be summarized as follows:

(1) BHC tends to penetrate into the edible portions of some agricultural crops with which it comes in contact. This is particu-

[14] Poos, F. W., Dobbins, T. N., Batten, E. T., and Boush, G. M., "Tests with Benzene Hexachloride for the Control of Insects Attacking Peanuts" (1946-1949), USDA. Bureau Ent. & Plant Quar. E-820 (1951).

larly true of peanuts, and has already been discussed for them, as well as other crops.

(2) Due to penetration we have been unable to develop any washing, peeling or inactivation procedure which will completely remove BHC residues or off flavors resulting from its presence.

(3) Processing in many instances tends to accentuate the off flavor of BHC and Lindane, and in certain instances off flavors continue to develop for some time after processing, while the produce is on the shelf. Bio-assays and chemical analyses have revealed that this off flavor is accompanied by a chemical breakdown of BHC to relatively nontoxic off-flavored materials of, as yet, unknown composition.

(4) BHC residues may remain in the soil for several years, and under certain conditions of continued application may tend to accumulate. Our own surveys in the Southeast and in California have established considerable soil contamination by this compound. Research by the Bureau of Plant Industry [15] has indicated that BHC put in the ground in September, 1946, persisted to December, 1949, at one-half its original concentration; in other words, this means that BHC in some soils may have a half-life of three years. Good research, based on accurate analytical methods, is needed to determine at what rates BHC is accumulating in those cotton soils of the South where other food crops may be grown in subsequent rotations, as well as in other areas—especially California—where soil contamination is occurring.

(*b*) Chlordane. A review of the available literature on off flavors from Chlordane largely confirms our own experience, that this insecticide, under certain conditions of use, may cause either an off flavor or a distinct difference in taste.

With respect to peaches and similar fruits, Chandler,[16] in attempting to control plum curculio with this compound, found that it conferred some off flavor to both the raw and cooked fruit. Likewise, Gould and others [17] noted off flavors of canned Stanley-type plums and canned Elberta peaches resulting from somewhat excessive and late-season applications. Rings and Gould [18] found that Chlordane

[15] Foster, A. C., "How Toxic to Plants Are Some of the New Insecticides?" 5 *Agric. Chem.* (8), 37, 39 (1950).

[16] Chandler, S. C., "Chlordan and Benzene Hexachloride for Control of Plum Curculio on Peach," 42 *Journal Econ. Entomol.* 514-518 (1949).

[17] Gould, W. A., Sleesman, J. P., Rings, R. W., Lynn, M., Krantz, F., and Brown, H. D., "Flavor Evaluations of Canned Fruits and Vegetables Treated with Newer Organic Insecticides," 5 *Food Technol.* 129-133 (1951).

[18] Rings, R. W., and Gould, W. A., "Effectiveness of New Organic Insecticides in Controlling Plum Curculio Infesting Plums," 44 *Journal Econ. Entomol.* 354-359 (1951).

controlled plum curculio on plums, but impaired the flavor of the fruit of at least one variety.

With respect to vegetables, Pepper [19] found that Chlordane treatment of soils for wireworm control imparted an off flavor to potatoes. This was later confirmed by Greenwood and Tice.[20] The same year, Wheeler [21] warned in the *Market Growers Journal* that Chlordane was similar to BHC, in that off flavors were being reported on potatoes and some other root crops grown on soils treated with this material, and that the effect may persist beyond the season of treatment.

On snap beans, Ellis and Clayton [22] found that soil applications of Chlordane for root knot control imparted a disagreeable odor. Later Ristich and Schwardt [23] detected off flavors in dried kidney beans grown on soils treated with Chlordane dusts for control of the seed-corn maggot.

Our experience with peaches, from experiments where Chlordane was used late in the season in excessive amounts, indicates that it imparts a flatness of taste similar to lack of sugar. Experiments with other products to which known amounts of Chlordane have been added prior to processing indicate, also, that Chlordane did not contribute a definite chemical off flavor in itself but rather, due to its presence, or that of its breakdown products, the taste buds were affected in such a fashion that their sensitivity to sweetness and, perhaps, other taste sensations, were decreased.

By means of a qualitative odor test, or by other means, we have detected Chlordane on California celery, New York cabbage and New York carrots.

As yet, we have no long-term data on the stability of Chlordane in the soil. Preliminary reports, from research started by the Bureau of Plant Industry [24] in 1949, indicate that Chlordane may persist in a relatively unchanged form for at least one year.

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[19] Pepper, B. B., Reed, J. P., and Campbell, S. C., "Investigations on Wireworm Control with Organic Insecticides in New Jersey," 26 *American Potato Journal* 315-325 (1949).

[20] Greenwood, M. L., and Tice, J. M., "Palatability Tests of Patotoes Grown in Soil Treated with the Insecticides Benzene Hexachloride, Chlordan, and Chlorinated Camphene," 78 *Journal Agr. Res.* 477-482 (1949).

[21] Wheeler, E. H., "Insecticides for Vegetables and Potatoes—1949," *Market Grower's Journal*, June, 1949, p. 20.

[22] Ellis, D. A., and Clayton, C. N., "Soil Treatments with New Insecticides Ineffective in Control of Root Knot," 32 *Plant Disease Reporter* 437-441 (1948).

[23] Ristich, S. S., and Schwardt, H. H., "Biology and Control of the Seed Corn Maggot on Beans in New York," 42 *Journal Econ. Entomol.* 77-80 (1949).

[24] See footnote 15.

(*c*) Other pesticides. We have experimental evidence from cooperative experiments in California that some of the dichlorophenol esters of benzene sulfonic acid, when used as miticides, have caused off flavors in string beans, grapes and unpeeled pears. Because of these, and other miticides for which we had no method of analysis or previous history of off flavor, we experienced a great deal of difficulty in the 1951 purchases of pears on the West Coast. Our original purchase-program called for between 1,000 and 1,500 tons of pears from California, but we were unable to complete this program because of the various miticides used. It was then necessary to purchase from the Yakima district in the State of Washington where, due to the higher price and added cost of transportation, we suffered a financial loss of between $20,000 and $30,000. We expect these materials to be used in considerable amounts according to California plans for this coming season. Therefore, unless satisfactory methods of residue analysis are developed, we will be forced to contract for Yakima pears again. I might say that the State of Washington is far ahead of the rest of the states in an insecticide program which produces quality produce with minimum residues. We have always had the best of cooperation from the Big Y, the Washington State Apple Commission and individual growers.

Recently on the West Coast, we had an unusual experience with one of the common dithiocarbamate fungicides, which, heretofore, we had considered perfectly safe for use on all crops for which it had been recommended. In this particular instance, following an outbreak of peppermint rust in the Willamette Valley and along the lower Columbia River, we cooperated with Oregon State College on an experimental program aimed at finding some fungicide which would control this disease. Preliminary experiments indicated that certain of the dithiocarbamate fungicides would give partial control, but we felt it necessary to run complete chemical analyses on the peppermint oil, and then correlate the results with flavor panel tests on chewing gum. Much to our surprise, we found that steam distillation had brought about a chemical decomposition of the dithiocarbamates to produce over 400 ppm of carbon disulfide in the peppermint oil. Subsequent flavor tests also revealed that this oil was off quality, from the standpoint of odor and flavor. Unfortunately, some of the peppermint growers who had heard of the favorable results obtained from the use

of these fungicides, were persuaded to apply them to considerable acreages, must against the recommendation of Oregon State College. The result was that we were forced to reject the oil, even though we needed it very badly at that time.

At about the time we ran into trouble with these dithiocarbamate type fungicides on peppermint, we found that certain English investigators [25] had reported that the presence of the spray residues of certain thiocarbamates stimulated the production of hydrogen swells in canned currants and, in some cases, adversely affected the flavor. Concurrently, within the past few years, we have encountered a type of accelerated corrosion in our baby-food closures, which we think may be partially due to certain nontoxic thiocarbamate-type accelerators used for vulcanizing the rubber gasket of the closures. Since then, we have very carefully scrutinized all products for dithiocarbamate residues not because of toxicity, but because of possible off flavors and the possibility of closure corrosion.

Cost of Maintaining Minimum Residues in Beech-Nut Foods

The cost of maintaining our quality standards with respect to pesticides has been considerable since 1946. The following table gives a breakdown of this expense to ourselves and the consumer by years, since 1946.

The Annual Cost of Pesticide Control in Beech-Nut Foods

Year	*Research and Quality Control*	*Agricultural Procurement*	*Processing Losses*	*Special Equipment*	*Total*
1946	.....	.....	$51,000	$7,000	$58,000
1947	$35,000	$20,000	30,000	7,000	92,000
1948	55,000	20,000	30,000	7,000	112,000
1949	85,000	20,000	30,000	7,000	142,000
1950	80,000	20,000	30,000	7,000	137,000
1951	70,000	20,000	30,000	7,000	127,000
				Total Cost 1946-1951	$668,000
				Average per year for six years	$111,333

The average annual cost of $111,333 per year is certainly a conservative figure, since we have had to direct the time and effort of our best research men to nonproductive problems, and have thus been deprived of their services in the development of new and improved products, which are the backbone of progress in a field as highly

[25] Adam, W. B., Dowson, W. M., and Marsh, R. W., "Effect of Organic Residues on Canned Black Currants," II. Ann. Report, Univ. Bristol Research Station, Campden (1947).

competitive as the food business. What does this mean to the final cost of our product? With peanut butter as an example, the cost of quality control and procurement for BHC-free peanuts amounts to five cents per dozen jars.

Need for More and Better-Coordinated Research on Pesticides

Most of the difficulties with residues, which we have described, have been due to their general use before sufficient scientific information was available on residue stability, residue penetration, development of off flavors in fresh or processed foods, their accumulation in soils, their effect on the over-all insect population, or the development of resistance in certain species of insects. The disturbed ecological relationships, which have often destroyed beneficial predatory insects, have allowed the buildup of other insect pests, which could not be controlled by normal spray procedures; this, combined with the development of resistance to specific insecticides, has resulted in control programs which have caused the buildup of excessive residues, in the hope of achieving control, and when this was unsuccessful, the hasty and, often, ill-advised use of new and more effective insecticides which had not yet been thoroughly tested. The net result has often been the creation of residue or off-flavor problems, more serious than those arising from the use of the original insecticide.

It appears that some of the economic entomologists who have been active in the development of certain ill-advised pesticide recommendations, have tended to become chemical specialists rather than entomologists. G. C. Ullyett [26] of the Commonwealth Bureau of Biological Control, Ottawa, Canada, says:

> Economic entomology is concerned with problems connected with insect populations which threaten the crops and produce of mankind. It deals with the control or limitation of those populations within the habitat in which they occur and is therefore primarily occupied with the problems which have an essentially ecological background. To be rational, therefore, the methods, employed in the course of its investigations, should be based upon a thorough cognizance of the ecology of the insect concerned.
>
> It follows that the economic entomologist should be thoroughly conversant with the principles, methods, and aims of ecology. Unfortunately, he is often lacking in the essential groundwork of this subject; or, if he has received adequate training, his professional career encourages him to ignore it in his daily work. *He ceases to be a biologist and, in the majority of cases, becomes in effect, a mere tester of poisons or an insecticide salesman.*

[26] Ullyett, G. C., "Insects, Man and Environment," 44 *Journal Econ. Entomol.* 459 (1951).

Along the same lines, Paul DeBach [27] of the Division of Biological Control of the University of California, Riverside, California, says:

> Insecticidal treatments for citrus pests have developed as emergency measures in response to immediate problems. Although such treatments have made it possible to raise commercial citrus crops, this immediate need has led to the neglect of fundamental studies of natural factors affecting pest populations. In many cases such treatments have resulted in no final solutions to pest problems; rather, repeated applications have been necessary in order to maintain control. Such repetition of treatment may indeed serve in time to intensify the problem. Such a result may occur through (1) the development of genetic cases of a pest resistant to the insecticide used, and (2) the reduction of natural enemy populations by the insecticide used.
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> The emergency then becomes self-perpetuating.

I wish to emphasize that the development of the new organic insecticides has largely taken place since the enactment of the current Food and Drug Act and that, by their very nature, they have created problems of misuse which were not anticipated when the Act was passed. We recognize that certain additional legislation may be necessary in order adequately to protect the public from undesirable residues. We are, also, of the opinion that such additional regulation could be kept to a minimum if provision could now be made for a carefully thought-out and well-coordinated program of research, aimed at anticipating and avoiding future problems arising from the expanded use of current pesticides, or the use of ones as yet undeveloped.

Testimony for Use of Pesticides

Much of the testimony presented in the past before the food and drug hearings, and at those hearings being held by your committee, has been devoted to establishing the necessity for use of pesticides. Very few of the agencies or organizations involved in the development and use of these new compounds have openly admitted that certain problems, similar to those encountered by our company, exist, nor have they offered a plan of action whereby they could be avoided in the future. I know that considerable funds have been raised to offset supposedly undesirable publicity against chemicals in foods. The action of your committee or other agencies, including those of us in the food industry who have felt that we were unduly burdened by the problems of pesticide residues, may have contributed to this feeling. On the other hand, it has been extremely difficult to raise funds, from either the food industry or the chemical industry, for research projects on residue problems in canned or processed foods. I admit that almost

[27] DeBach, P., "The Necessity for an Ecological Approach to Pest Control on Citrus in California," 44 *Journal Econ. Entomol.* 443-447 (1951).

everyone is interested in attending committees formed to discuss mutual problems. Perhaps we have too many committees, all subject to pressure from special interests, but be that as it may, most companies are loath to contribute money to a research project, no matter how well-organized and supervised, which may show that a competitor's product has certain advantages superior to theirs. This is human nature, and should be recognized as a distinctly limiting factor to far-reaching cooperative research supported entirely by industry.

Proposal for State and Federal Cooperation

On the other hand, we are paying state and federal taxes to support state experiment stations and various bureaus, such as the Bureau of Entomology and Plant Quarantine, within the USDA, which have and are taking the direct responsibility for testing and recommending various pesticides for use. We recommend, therefore, that, along with any proposal for new legislation, due consideration be given by Congress to the development of a coordinated program of testing between the USDA and at least four of the key regional state experiment stations. Each new pesticide which shows promise of commercial use should be thoroughly investigated in accordance with a definite plan of procedure with respect to methods of residue analysis, residues at time of harvest, off flavors, methods of residue removal, stability of soil residues and their effect on crops, their possible effect on insect ecology, etc. If this could be achieved, most state recommendations could be made on a sound scientific basis, with corresponding protection to the farmer, the food processor and the consumer.

With regard to toxicological testing, it would seem that a better co-ordination of research could be achieved if the United States Public Health Service were empowered to expand their program in cooperation with the chemical manufacturers. The United States Public Health Service has the technical personnel, facilities and experience for doing this work and, if properly administered, it would seem that they would be in better position than the Food and Drug Administration to establish proper tolerances. We are firmly of the opinion, however, that the Food and Drug Administration should have full responsibility for the enforcement tolerances under either existing or future legislation.

Basic Requirements for Control of Pesticidal Residues in Foods

With regard to legislation aimed at the control of pesticidal residues in foods, there are certain basic requirements which we consider essential; they may be summarized as follows:

(1) Evidence of adequate toxicological testing.

(2) The development of suitable methods of pesticidal residue analysis in order that the farmer, the food processor and the consumer be protected against accidental or intentional misuse of toxic pesticides. The manufacturer of pesticides should be required to present a suitable method of residue analysis prior to registration for sale.

(3) General information on the approximate range of residues occurring on or in produce at the time of harvest. This should include data covering adequate pretesting for off flavors in fresh or processed foods.

(4) Some general recommendations, based on the known chemical and physical properties of the pesticide as formulated, regarding the development of adequate methods for removing excessive residues.

(5) A requirement that the Food and Drug Administration, once a pesticide is registered, establish and publish a tentative tolerance in the *Federal Register,* within 90 days following registration.

(6) A requirement that following the publication of tentative tolerances, the Food and Drug Administration make sample analyses of interstate shipments of fruits and vegetables, and if the tentative tolerances are exceeded, issue public warnings to the areas of production concerned.

(7) A requirement that if the tentative tolerances are still being exceeded after a 90-day warning period, the tentative tolerances be made official and seizure proceedings instituted. **[The End]**

Chemicals in Foods Legislation

By FRED BARTENSTEIN, Jr.

This Address Was Delivered at the Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association Held in New York, New York, January 23, 1952

MY GROWING ADMIRATION for many of the procedures followed by federal government people on difficult subjects prompts me to state at the very beginning of this paper that the views expressed in it are not necessarily those of the other members of the chemicals committee of this section nor of this section itself, nor of any trade association, nor of any chemical company including Merck, nor of any food company, nor of the federal government. Truly it can be said, I *think*, that on this highly controversial and expansive subject, any ideas expressed are my own.

The Delaney Congressional Committee to Investigate the Use of Chemicals in Food Products began its hearings in November, 1950. The committee made an interim report to the House of Representatives in January, 1951, offering the tentative conclusion that existing federal laws dealing with the use of chemicals in foods are not adequate to protect the public against the addition of unsafe chemicals. The committee reported that the food chapter of the Federal Food, Drug, and Cosmetic Act should be amended to include a section generally similar to the new-drug section of that Act. Further opportunity, said the committee, should be given to those affected by such legislation to present their views and to comment on proposed legislation before any specific recommendations were made to Congress.

In response to the Delaney Committee's request for suggestions as to how the Federal Food, Drug, and Cosmetic Act should be changed to provide adequate control over the use of chemicals in food,

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the Food and Drug Administration prepared a draft amendment. This draft was adopted by Representative Miller, a member of the Delaney Committee, and submitted to Congress in March, 1951, as H. R. 3257.

At the same time, the chemical industry, primarily through the Manufacturing Chemists' Association, has been at work on draft amendments to existing laws that would serve the purpose of strengthening them. Members of the food industry have shown an active interest in these efforts, and have cooperated in making further suggestions, so that today there is a fairly tangible synthesis of industry views on specific legislative proposals.

Existing sections of the Federal Food, Drug, and Cosmetic Act, the Federal Insecticide, Fungicide, and Rodenticide Act, and their state counterparts contain specific provisions affecting the delivery and use of food ingredients and possible food contaminants. Acting under these laws, the industries and their governing agencies, the Food and Drug Administration, and the Department of Agriculture, have done a good job of bringing safe and nutritious foodstuffs to the nation's table.

I have now walked completely around the subject of chemicals in food legislation, and can tell you that it lies inside those boundaries. In passing, this subject reminds me of an old, old story—and older because I have told it to so many who already knew it—of the lost traveler looking for a small town in Virginia. He was finally told in desperation by a direction-giving native: "I don't believe you can start there from here." The most difficult part of any discussion of this subject is, in fact, the finding of an appropriate starting place. In this discussion I will first review present laws, then the proposed changes in them.

Present Laws

Because of Section 402 of the Federal Food, Drug, and Cosmetic Act, it is illegal to deliver in interstate commerce any food containing an added poisonous or deleterious substance. If required in the production or manufacture of food, however, any such ingredient, in accordance with Section 406 of that Act, may be allowed in quantities found by the Federal Security Administrator to be safe to food consumers.[1]

Likewise prohibited from interstate commerce because of Section 402 is any food from which a valuable constituent has been removed, or in which there has been a substitution of ingredients, or in which damage or inferiority has been concealed in any manner, or to which a substance has been added to make it appear better than it is, or which bears a coal-tar color other than from a batch certified by the Food and Drug Administration, or whose container is composed of any poisonous or deleterious substance that may render the food injurious to health.[2]

Manufacturers of foods and food ingredients bear the responsibility of making their products comply with these legislative standards, as they must make them comply with other adulteration and misbranding standards set up in the Act. This means that they must conduct such tests as are necessary both to satisfy their own requirements of making and vending products that will harm no one, and to avoid subsequent injunction, seizure or criminal penalty actions by the Food and Drug Administration. The result of these provisions is rather well-beaten tracks to the toxicological laboratories of the nation and to the door of the Food and Drug Administration Division of Pharmacology. It is not surprising that those who have worn those paths have sometimes found it hard to understand the claim that there are no adequate laws covering the subject of chemicals in food.

The Federal Insecticide, Fungicide, and Rodenticide Act, unlike the Federal Food, Drug, and Cosmetic Act, deals with substances that

[1] Although the power to establish safety tolerances for substances required in food production and manufacture under this Section 406 has not been used to any great degree, extensive hearings were conducted by the Federal Security Administrator in 1950, looking toward the setting of tolerances for substances used prior to harvest in the production of fruits and vegetables.

[2] Under Section 401 of the Federal Food, Drug, and Cosmetic Act, the Federal Security Administrator has the power to establish definitions and standards of identity for manufactured foods. The purpose of the food-standards section is to promote honesty and fair dealing in the interest of consumers. Although the practice of the Administrator in promulgating these standards has been to accept toxicological evidence and to limit ingredients considered by him as unsafe, the procedure was not originally intended for the determination of matters controlled by Section 402 of the Act.

are not themselves foods, but that are used in conjunction with food production or processing and which, for that reason, may subsequently appear in foods as residues. No substance covered by that Act may be delivered in interstate commerce until it has been registered with the Department of Agriculture. The application for registration must include the name of the substance; its labeling; all claims to be made for it, including use directions; and, as the Department requests, the formula of the substance and a description of the tests made upon which the claims are based. The department may turn down the application if the substance does not comply with all provisions of the Act, including (1) failure of its labeling to contain directions for use which are necessary and, if complied with, adequate for the protection of the public, or caution statements which are necessary and, if complied with, adequate to prevent injury to man, and (2) its being injurious to living man or other vertebrate animals when used as directed or in accordance with commonly recognized practice. The applicant has the right to have his product registered under protest, but thereafter the department can proceed under the Act for any violation of its provisions.[3]

Miller Bill

The Miller Bill would give to the Federal Security Administrator added means to ensure the safety of food not only by increased control over the food itself, but by new power over substances used by food producers and processors. That power is the outright prohibition of the shipment of such substances in interstate commerce, or the shipment of food containing them, until the shipper or user has satisfied the Federal Security Administrator that they have been adequately tested for toxicity and are safe for use.

The bill defines these substances as those intended to be used (1) to preserve or alter any food or food characteristic; (2) as a substitute, in whole or in part, for any food or food ingredient; or (3) for any purpose in food production or handling if likely to result in contamination of the food.

This language covers practically all materials used in food production at any stage of the food's movement from farmer to consumer. Since any ingredient added to a food probably preserves or alters it or at least one of its characteristics, all intentionally added ingredients

[3] Since the Federal Insecticide, Fungicide, and Rodenticide Act was passed in 1947, it is reported there have been only a few registrations under protest out of many applications considered by the Department of Agriculture, but none in which the issue in dispute concerned safety to food consumers.

of food would seem to be covered. These include, by way of example, preservatives, minerals, vitamins, seasonings, flavorings, colorings, shortenings, baking powders and vegetable oils. Also, all materials used in conjunction with food production, processing or holding would be within the law's coverage if likely to result in contamination of food—for example, fertilizers, insecticides, fungicides, herbicides, machine oils and greases, detergents, cleaning compounds, containers, bags and wrappings.

Inadequately Tested Substances

Every such substance which is not generally recognized among toxicity experts as having been adequately tested to show that it is not "poisonous or deleterious", or if poisonous or deleterious and required in food production, has not been adequately tested to show that it is "safe" for such use, is designated a "chemical additive"—whether or not it is a chemical in the ordinary sense of that term—and requires an effective application prior to delivery or use.

In order to obtain an effective application, the seller of the substance or the producer of the food who wants to use or continue using it, must file with the Federal Security Administrator a statement of its intended use and, among other information, full reports of toxicity tests conducted on it. The application becomes effective in 60 days unless the Administrator turns it down, but he may postpone his decision for 180 days, in order to study the data. The application is denied if the Federal Security Administrator comes to any of the following conclusions after giving the applicant an opportunity for a hearing:

(1) Adequate tests have not in his opinion been conducted to show that the substance is not poisonous or deleterious.

(2) If found to be poisonous or deleterious, adequate tests have not in his opinion been conducted to show safety.

(3) If found to be poisonous or deleterious, the tests show in his opinion that it is not safe.

(4) If found to be poisonous or deleterious, the tests do not show in his opinion that it is safe.

(5) Methods of analysis to determine residues are in his opinion inaccurate or incomplete.

(6) There is not enough information available in the opinion of the Administrator to allow him to determine whether the additive is poisonous or deleterious or, if so, whether it is safe.

If an individual applicant feels that the Federal Security Administrator in refusing to make an application (some call it a "supplication") effective, or in refusing to terminate the suspension of an application, has decided any of the above questions wrongly, he may within 60 days appeal to the United States court of appeals. The question before the court, of course, is not whether the application should or should not be made effective, but whether the Administrator came to the wrong conclusion on any one of the above issues in turning the application down. All findings of fact by the Administrator, if supported by substantial evidence, are binding on the court. Except for being subject to review by the Supreme Court of the United States, the judgment and decree of the court of appeals is final.

Other Proposals

Questions have been raised by some members of the food and chemical industry whether the Miller Bill medicine is not a rather toxic dosage, even assuming the Delaney Committee's tentative diagnosis to be a correct one. In fact, these persons feel the disease is not nearly so virulent as has been proclaimed by some of its diagnosers. One wonders, for example, whether the Food and Drug Administration would approve the Miller Bill under the new-drug section as safe for use for the conditions named, in view of its rather far-reaching side effects.

To be more to the point, the Food and Drug Administration feels that it has a difficult enforcement problem under present laws for two reasons, as I see them. Both of them arise, says the Administration, not from reputable and responsible food and chemical companies, but from fringe operators who are unaware of or try to skirt the law. These difficulties are (1) that a substance may be added to a food and the food consumed before the agency learns about it and (2) that once the Administration learns about the use of the substance, it is not able to act effectively if it does not know whether the substance is in fact poisonous, deleterious or unsafe.

Industry representatives have applied themselves to these questions. The Manufacturing Chemists' Association, with help from food companies, has labored and still labors diligently on what may be called a notification proposal. This would forbid the delivery in interstate commerce of any food containing an intentionally added substance that has not theretofore been so used in food until there has been submitted to the Food and Drug Administration a statement of

its composition, samples, use directions, method for determination of how much of the substance remains in or on the food, and the results of all toxicological investigations conducted on it to show safety. Under the proposal the food could not be shipped for a specified period afterwards—say 60 days—giving the Food and Drug Administration time to study and analyze the submitted information. This information may be filed either by the shipper or user of the ingredient. As a practical matter, it probably would be filed in most instances by the producer of the ingredient.

Officials of the Food and Drug Administration have taken the position that mere notification is not enough; that there must be some way to stop immediately the marketing of food bearing or containing a substance that has not been adequately tested and shown to be safe. The MCA proposal as it now stands is, of course, more than mere notification. The results of all safety studies conducted must be submitted with the notice. If a food is shipped in interstate commerce without the prior submittal of this information, it could be immediately seized and condemned, or an injunction secured, or criminal penalties obtained for violation of the Act. If the Food and Drug Administration feels after the data is submitted that the substance is not safe, it may proceed under existing sections of the law to seize the food, obtain an injunction or bring criminal penalties, but in this case having the advantage of all the data or lack of it on which to base its action.

Also included in the MCA proposal is a provision for an informal administrative conference, to be called at the request of either the industry or government, to give the appropriate experts of each opportunity to air their differences respecting the adequacy and results of safety tests, and to iron them out.

Presumably, if the data submitted in accordance with this notification proposal were to be adequate in all cases to show that substances are safe for use, the Food and Drug Administration would not press for more, since it feels that as to ingredients whose toxicity is known, the present law is adequate. To the extent that the Administration does not agree with the notifier that the tests are adequate or the substance proved safe, however, the Administration apparently believes that it should have the power to prevent sale or use altogether until satisfied on that point. I think that here we have arrived at the fairly narrow issue from which most of the difference of opinion springs. The Food and Drug Administration believes that it should be the final arbiter as to safety of these substances, meaning that it

wants the power to establish what the testing methods shall be for each food ingredient and what the testing standards shall be, and the power to decide whether each substance has been so tested and meets such standards.

It is true that the agency has similar powers under the new-drug section of the Act and has so far exercised them with judgment and restraint, and in a manner that reflects credit upon its present administrators. In the case of new drugs, on the other hand, there is an ever-present atmosphere of medical urgency pressing the agency to approve a new product. Safety questions are generally limited to the acute-toxicity phases, since drugs are typically used for short, emergency periods, and these questions can be weighed against humane and often life-saving advantages.

Setting Food-Substance Standards

There would not seem to be much doubt that in approving the safety of food substances, on the other hand, tremendous elements of indecision will assail the agency, primarily in setting its standards for chronic-toxicity tests for substances whose need is not convincing to it. A virtually uncontrolled power to set the standards, combined with doubts as to the utility or necessity of any substance, would seem to result in a serious risk of inaction. Nor does there seem to be much doubt that without the offsetting medical need that surrounds new drugs the agency would tend to establish its standards so high as to protect itself against any subsequent criticism.

The important fact is that the standards, methods and test interpretations will be what the Administration says they shall be, and these will not necessarily be what the best scientific minds or the most informed judgment say they should be. The courts at the same time will be bound by the Administrator's facts. This reminds one of the conversation in *Through the Looking Glass* between Alice and Humpty Dumpty. "But 'glory' doesn't mean a 'nice knock-down argument'," Alice objected. "When *I* use a word," Humpty Dumpty said, in rather a scornful tone, "it means just what I choose it to mean—neither more nor less." "The question is," said Alice, "whether you *can* make words mean so many different things." "The question is," said Humpty Dumpty, "which is to be master—that's all." Many manufacturers probably would be less concerned by the Miller Bill were the Food and Drug Administration to be truly a referee deciding the facts, and not a body also deciding in its discretion as the game progresses what the rules shall be.

The MCA proposal would leave the court to decide, on the basis of all evidence presented, whether a food substance is poisonous, deleterious or unsafe, taking into consideration appropriate scientific testimony from both government and industry.

Another solution to this issue has recently been suggested—that the notification plan be supplemented by a special injunction feature. Under it the Food and Drug Administration would be given the privilege of seeking an injunction forbidding the marketing of any food containing an additive that may jeopardize the public health. An important feature in this proposal is that the issue before the court would not be that an ingredient is unsafe, but that it is a jeopardy to health because, among other reasons, it has not been adequately tested to prove its safety. Although opposition to this proposal has been widely expressed, it contains important elements of possible compromise. The government would not be stopped from taking action as a result of not having knowledge of the toxicity of a substance. It could act to stop delivery of a food containing the substance on the grounds, among others, that toxicity experts do not consider it as having been adequately tested. On the other hand, the government agency is not given an absolute power to set its own standards, but must be able to convince an impartial court through traditional procedures that an act detrimental to public health will be committed unless an injunction is granted.

Status of Pesticides

As to present laws governing pesticides: It seems inappropriate to give to the Food and Drug Administration added power over pesticide substances. This agency has been concerned with the delivery of food substances themselves, including any residues on them, but not with the delivery of products unintended for food use. Insecticides are no more foods than are food-processing machinery, farm trucks, gloves and picking sacks. It would seem to be an illogical extension of one government agency's jurisdiction to give it separate and distinct control over precisely the same substance that is already controlled by another government agency. On the other hand, to the extent that existing provisions of the Federal Insecticide, Fungicide, and Rodenticide Act may not clearly give the Department of Agriculture authority to pass on the safety of pesticides with respect to ultimate consumers, there would seem to be no reason why it should not be clarified.

Conclusion

Some persons believe that a full licensing power over the sale and use of food additives with respect to safety should be placed in government hands. It is human for government representatives themselves to believe that, given complete authority, they can solve all the problems. So, too, is it human, of course, for each food and food ingredient producer to believe that it is unnecessary to regulate him at all. To the extent that neither is endowed with wisdom and judgment of the Almighty, they must forego those prerogatives, and that is the tradition on which our government system is built.

It is true that the Food and Drug Administration has exercised with judgment and restraint its licensing power over the limited field of new drugs, where safety has more definite criteria and medical needs afford a compelling urge to act. It does not follow that such is the proper pattern for the handling of the enormously extensive area of food ingredients and possible food contaminants, nor a proper pattern for any further extension of government control over industry.

The public suffers in the long run and the character of the democratic process is impaired, to the degree that laws give government the power to make supplicants of the governed. A fair and effective law can be written that affords full and complete power to protect the public health from any improper use of food substances and that, at the same time, does not continue an offensive trend toward more parental government. It behooves all of us to make outstanding efforts to achieve that end. **[The End]**

• *INTRODUCTION OF FAIR-TRADE BILLS IN CONGRESS* •

Three new bills have been introduced. S. 2522 would amend the Sherman Antitrust Act to permit enforcement of fair-trade prices against nonsigners and exempt such enforcement from Federal Trade Commission Act prohibitions, and would constitute the act of selling below a fair-trade price an act of unfair competition in interstate commerce. H. 6367 would also amend the Sherman Act, establishing an action for damages or injunctive relief against a nonsigner selling below a federal-trade price, excepting treble-damage action. H. 6184 would legalize enforcement of fair-trade prices against nonsigners through amendment of the Federal Trade Commission Act.

Chemicals in Food

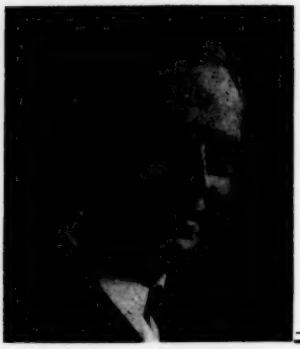
By R. C. NEWTON

This Is the Full Text of a Paper Prepared for Delivery at the Inter-Industry Conference on Chemicals in Foods, Sponsored by the Manufacturing Chemists' Association. At the January 15 Meeting, However, Time Permitted Only a Summary, During a Floor Discussion, of These Remarks

I AM GLAD to have had the opportunity to sit in on this conference and hear the many diverse views on this important question. This subject is of tremendous importance to the food industry, and while it may be of considerable importance to the chemical industry, it occupies there, perhaps, only a minor role. The food industry of this country is immense. When considered on the basis of tonnage or dollar sales, the figures are tremendous. When reviewed from the point of view of numbers of producers, processors and distributors, it is equally large, but when viewed from the standpoint of the dependence of the American people for their very lives, it reaches its peak of importance.

No one company nor, in fact, no one segment of the industry can be considered as representative of the food industry in its entirety. There are, however, some problems which are common to a very great extent across the entire industry. There are certain responsibilities which fall directly upon any person who processes or distributes food to the public.

One of these responsibilities is to see that the food product reaches the ultimate consumer in a condition that will provide nourishment and, at the same time, present no hazard from its consumption. The fulfillment of this responsibility requires not only facilities, but also a great deal of technical knowledge and, above all, a high standard of ethics for public welfare. There are many companies in the food industry which have sufficient technical knowledge; there are, also, many that subscribe to such high standards of ethics, and we hope there are increasingly more who can qualify on both scores.



The Author Is Vice President of Swift & Company, in Charge of Research

The manufacturing chemical industry, under whose sponsorship this meeting was called, has made a brilliant record in the production of new and useful things for the betterment of mankind. One of the outstanding characteristics of this chemical industry is the speed with which new developments are adapted to human needs. However, in the application of science to food, speed is of less importance than safety.

It is not clear from the publications emanating from the chemical industry over the past two years that many of the members of this industry understand why a new material cannot be adapted to the food industry as quickly as it can to plastics, textiles, etc. The tone of many articles appearing in such sequence as to indicate direct propaganda have been obviously prepared by persons who do not have full realization of the delicacy of balance of chemical reactions within the human body and the ease with which foreign substances can throw this delicate mechanism out of balance.

Running through this series of propaganda articles are many unsound premises. The repetition with which these same erroneous issues appear would indicate a planned objective of confusion. I should like to mention five of these issues:

The first, and perhaps the most frequent, is that of natural v. synthetic. There are those among these writers who would have us believe that the issue centers around this point. I should like to deny emphatically that this question has anything whatsoever to do with the problem of chemicals in food. Surely, no one denies that many substances growing in nature are poisonous to the human being, so that once and for all can we say that it makes no difference whether a poison is natural or synthetic, it still should be kept out of food.

The second erroneous issue is that of persecution. There is a vein of implication in many of these articles that the manufacturing chemical industry is being persecuted. Insofar as I know, this is also false and should have no part of the real consideration of this important question.

The third confusing bit of philosophy is that all foods are chemical in nature. Of course they are all chemical in nature, but that does not lead to the conclusion that all chemicals are satisfactory as foods.

Number four—you cannot prove a negative. This has been used to belittle the requirements for an adequate animal testing program before new and unusual substances are allowed in food products. Whether you can prove a negative or not is beside the point, for you can get good substantial evidence that a substance is poisonous, the extent of its poisonous quality, and the hazard presented by its incorporation in food. You cannot always do this in a few weeks. It is a two-to-three-year program, and since it is usually begun only after a thorough screening of a large number of substances, the total time very often runs to five or six years. With the rapid rate at which new substances are proposed for incorporation in foods, is this too great a penalty to pay for the safety of the public? I contend that it is not.

The fifth of the confusers is that even table salt is poisonous under some conditions. I think it is well established that one can cram enough table salt down his throat to kill him, but is there any doubt in the mind of any one here that table salt used by the normal individual in the manner which it has been used for thousands of years represents any hazard?

Conversely, is there any doubt in any one's mind that it is possible to incorporate in food products small amounts of chemical substances which, without being obvious to the consumer, would either kill him or impair his health when consumed over a long period of time?

The real issues, and the only issues that are worth discussing in connection with this problem at the moment, relate to pretesting of new and unusual substances proposed for food. I would like to list them in the order that they occur to me:

(1) Shall the unusual products proposed for use in food (be it natural or synthetic) be subjected to animal testing before trying them out on the public?

It is my experience that no one is bold enough to stand up in meeting and suggest that all these unusual substances be tried on the public without pretesting. Many, however, will have certain qualifications they wish to put in. They will object to the long test period. They will object to the levels that are included in the test. They will object to the interpretation of results. They will object to delegating authority to a government body to serve as a referee on the adequacy of such tests.

(2) Should such pretesting be compulsory?

There are many who will laud the ethical standards of the chemical industry and the food industry in an attempt to show that they are reliable and intelligent enough to make all the tests required without compulsory action. A moment's reflection on the part of anyone should convince him that this is not true.

(3) What constitutes a good and sufficient test?

It is my own opinion that there is a lot yet to be said on this point. The Food and Drug Administration has attempted to outline the test requirements. They have recognized that each individual case calls for some modification and it is possible that as the years go on we will arrive at a clearer understanding of what should be required to protect the public.

(4) Who should decide when the testing has been adequate and that the product is harmless?

There are those who have proposed establishment of an unbiased, nongovernment scientific body to referee these questions. It seems obvious to me that such authority can only be delegated to a government appointee, and that brings us right back to the present regulatory bureaus in the government. One of these is the Meat Inspection Division of the Bureau of Animal Industry. This regulatory bureau now has all of the authority to require pretesting. The Food and Drug Administration has authority to require pretesting on anything to be added in those foods on which standards and definitions have been promulgated. It does not have authority, under the present law, to require pretesting on a proposed additive in a nonstandardized food, nor does it have authority to stop the use of that additive unless it can prove that the additive is deleterious. Since this is obviously an

impossibility, as the Food and Drug Administration could not maintain a staff large enough to test all of the chemicals that can be thought up by the manufacturing chemical industry and the entire food industry, it seems only logical that the burden of proof should be reversed and put upon the industry rather than upon the government.

I noticed in the December 24 issue of *Chemical and Engineering News* that the Manufacturing Chemists' Association has raised a sum of money for public relations activity. This article states that the contributions were made "because of the emergency nature of the chemicals in food problem." I am particularly interested in this activity of the Manufacturing Chemists' Association because I have spent all of my business life in the food industry, and feel that I have a real stake in any matter that may affect the food industry. If I may judge from the numerous articles and editorials occurring in the chemical journals during the past year, I believe there is a real threat to the food industry. I base this assumption on the possibility that these articles, which appear in such sequence of repetition that they appear to be propaganda, may eventually affect public opinion to such an extent that the Food and Drug Administration will be prevented from carrying out its responsibility of protecting the public. If this series of events should come to pass, there will, undoubtedly, be a surge of new chemical substances incorporated in food without adequate pretesting.

Such a program will lead to a disaster, just as surely as we are assembled here today. Such a disaster will reflect discredit to the food industry; incidentally it will also reflect discredit to the chemical industry, but the principal damage will be done to the public. After such a disaster, there is no doubt that the law will be strengthened in any manner considered necessary for public safety.

With these hazards to public health and this threat to the prestige of the food industry, as well as the chemical industry, is it too much to hope that the Manufacturing Chemists' Association in their public relations program will do nothing to inhibit the Food and Drug Administration in its effort to protect public health? Also, may we hope that part of the activity of the Manufacturing Chemists' Association will be directed toward the education of its own members who may not understand clearly their responsibilities? **[The End]**

Improvement in Nutritive Value of

The Opinions Expressed in This Report, Which Was Presented to the Inter-Industry Conference on Chemicals in Foods, January 15, Are the Personal Views of the Author. He Is Research and Development Vice President of Pillsbury Mills, Inc., Minneapolis, Minnesota

NUTRITIONALLY valuable chemicals deliberately added to several classes of staple foods are of tremendous benefit to the health of men, women and children throughout this country. To a nutrition specialist, all classes of foods are chemicals whether produced by synthesis either through plants, animals or through special manufacturing processes. The only known differences are that natural processes produce mixtures, whereas factory processes usually produce single concentrates. The cells of our bodies utilize the respective vitamins, minerals or other compounds similarly, regardless of how the requisite atoms were made into the vital molecules.

Our most basic universal nutritional needs are for simple chemicals, particularly for oxygen through the lungs to our blood each minute of life. Water and salt, likewise chemicals, come next in constant demand. Each one is a pure chemical and is even more continuously needed than the well-known proteins, fats and carbohydrates.

For this report I wish to focus our attention on four or five of the major nutritional improvements brought about over the last 120 years through the addition of chemical concentrates to well-known staple foods. Nutritional fortification of foods is a long-established practice both here and in countries abroad.

Iodized Salt First Food Fortification

Food fortification with pure chemicals really had its start about 1833 when the French chemist, M. Boussingault, published an article on the iodine-containing salts of the Andes mountain region of South

ıe of Foods

Shelburne Studios, Inc.

By FRANK L. GUNDERSON

America (*"Memoirs sur les Salines iodiferes des Andes"*).[1] He often observed goiter in children in the high altitudes in contrast with the lower incidence nearer the seacoast. Although he was a chemist by profession, Boussingault was actually working in the field of minerology high in the Andes Mountains of South America, when he was inspired to write the classical recommendation which, translated to English, reads as follows:

> In the very high places, and where consequently the water cannot be saturated completely with air because of the reduction of atmospheric pressure, I have proposed to introduce the use of salt from iodine-bearing salt-mines or to introduce into ordinary salts a certain quantity of mother-water of these salts.

Soon thereafter iodization of table sale was started in France and later in many other European countries with varying degrees of success. It is quite possible that the amounts have in some instances been unnecessarily high and in others too low for effective results. Also for many years the iodides which were added were not stabilized and this led to dissipation of the iodine during shelf life or storage of the iodized salt. Iodized salt in each of the countries has been used by only part of the people who have needed it. Thus the percentage of people protected against endemic goiter has varied widely.

In this country Doctors Marine and Kimball[2] in 1917 first published an important report based on their work in the city of Akron, Ohio, entitled *The Prevention of Simple Goiter*. A proper amount of iodine in the food through the first 12 or 14 years of life would prevent entirely those troubles which are typical of children particularly in the so-called

[1] Boussingault, M., "Memoirs sur les Salines iodiferes des Andes," *Annales de Chemie Et de Physique*, 54:163-177.

[2] Marine, David, and Kimball, O. P., "The Prevention of Simple Goiter," 3 *J Lab. & Clin. Med.*, 3:40-46 October (1917).

goiter belts of this country—namely, the areas around the Great Lakes and the Pacific Northwest portion of this country.

Iodized salt was first made available as a grocery-store product in 1924 as a result of the recommendations of goiter-study groups in Michigan and Ohio growing out of the work of Doctors Marine, Kimball and others. Part of the table salt used in this country is iodized by the addition of potassium iodide at the uniform level of 0.01 per cent (100 parts per million, "p.p.m.") and with also minute amounts of certain stabilizers added to prevent the dissipation of the iodine from the salt. Dr. Kimball and others have told me recently, and the medical and public health publications emphasize this point, too, that although the iodization of table salt on a voluntary basis has brought protection to some people, it is not yet reaching a high enough percentage of the people. Currently, something like 50 per cent of the table salt eaten in this country is of the iodized version. The purchase of iodized or uniodized table salt is an elective matter with the individual housewife. Although there have been strenuous educational campaigns at frequent intervals since 1924, there are still too many people who do not appreciate the necessity of using iodized salt. Thus, many hundreds of thousands of children are needlessly afflicted with varying degrees of endemic goiter. Although a few instances of skin disorders of the acne type have occurred, it is stated on good medical authority that not one single instance of harm to a person has been proven to result from iodized salt. In spite of the overwhelming evidence in favor of iodized salt, a legislative bill to make iodized salt mandatory on a national basis failed in a committee of Congress only two or three years ago. Meanwhile, Canada and England have recently taken steps to make the iodization of table salt mandatory so that all of their people will receive it regularly—Canada at 100 p.p.m., and England at 15-30 p.p.m. Our voluntary level is 100 p.p.m.

Personally, I have two suggestions which arise out of the study of the records and of well-informed opinions available to me from this country and from several foreign countries—namely, (1) that the mothers and fathers of young children be further and repeatedly urged to use iodized salt for dining-table purposes and (2) that now, in view of the fine degree of stablization which has been effected in the iodized salt of the United States, and the current knowledge of the amount which will suffice to prevent endemic goiter, we might well review the quantity which is added, with the ultimate objective of lowering the amount to one-half of its present level, or in other words lowering

the standardized amount from 0.01 per cent down to 0.005 per cent or 50 p.p.m. of potassium iodide in table salt. The lower amount should suffice and it would effect a practical economy.

Vitamin A Fortification of Margarine

During World War I Denmark shipped practically all of its butter to England. Unwittingly the Danes went too far in exporting vitamin A without otherwise bolstering the vitamin A content of diets at home. The results were severe.

The vitamin A deficiency which manifests itself in children is known as Xerophthalmia. Vitamin A is a specific nutrient requirement for nourishment of the tissue of the eyes. Vitamin A deficiency also manifests itself in abnormally high incidence of respiratory infections, and in impaired growth of children. With such dire results, the Danes quickly moved to add vitamin A concentrates from fish liver oils to their supply of margarine. Since that time Denmark has been practically free of vitamin A deficiency. Sweden and England soon took up the addition of vitamin A to margarine. Subsequently the margarine industry in this country has voluntarily adopted the practice and currently fortifies more than 98 per cent of its total output with vitamin A up to the standardized level of approximately 15,000 units per pound. This is equivalent to the amount of vitamin A present in butter produced from milk of pasture-fed cows.

The margarine fortification program is going along successfully. I do not foresee any particular problem in that connection. So far as I can discern, it makes little difference whether the vitamin A concentrate utilized for margarine fortification is synthesized by fish or is the newer form [2a] now factory-made by skilled chemists. Since applied nutrition is dependent also on economics, I would favor that form of vitamin A which is available at lower cost. Both types of vitamin A are believed to have exactly equal physiological value.

Vitamin D Fortification of Staple Foods for Rickets Prevention

Another nutritional necessity and urgent requirement for all growing children is vitamin D, the rickets-preventive vitamin. The chest, pelvis and likely all other bones of rachitic children are badily malformed so as to be permanently unsightly and functionally damaged.

[2a] The present legal standard provides only for fish liver oil or a concentrate made therefrom as the source of Vitamin A for this purpose.

The ultra-violet irradiation of milk to activate its natural sterol into effective vitamin D was begun about 1930. Since that time an increasing proportion of evaporated milk and of bottled milk have been given vitamin D nutritional properties. Since children need about 400 units of vitamin D per day, that is the amount of the vitamin which is customarily incorporated in a quart of bottled milk or in the amount of evaporated milk equivalent to a quart. More recently the direct irradiation of milk or of evaporated milk by ultra-violet lamps has been supplanted by the addition of vitamin D-activated concentrates to the milk.

As to the trend in the production of vitamin D milk, Dr. W. E. Kraus, professor at Ohio State University and chairman of several committees of the National Research Council, Washington, is reported to have said recently:

> One large milk company, operating over a wide geographical area, reports that in 1941 vitamin D milk sales represented 12.7% of the total fluid milk sales, and that in 1949 this figure had increased to 57.3%.

Another statement on good authority is:

> Vitamin D homogenized milk sales represent from 50% to 95% of total milk sales, depending on markets.

Regarding the nutrition of rural children, it is interesting and gratifying to know that an increasing number of farmers today deliver all of their milk to processing plants and purchase their daily milk supply for their family table use at the processing plant. This is believed to be a result of the farmers' appreciation for the greater safety of pasteurized milk and for the additional food value imparted through the added vitamin D.

Informed opinion in medical and nutritional circles is overwhelmingly to the effect that florid rickets, which was quite common even so recently as 20 to 30 years ago, has today almost entirely vanished. While some of that improvement can be attributed to more extensive use of pharmaceutical preparations, it is probable that a large part of the improvement is the direct result of vitamin D fortification of evaporated milk and of bottled milk.

In a private report from the American Medical Association I am advised:

> It is little short of miraculous to recall that in the mid-20's florid rickets was commonplace; in fact any sizeable children's hospital had a ward full and could demonstrate, on a moment's notice, a great variety of rachitic lesions. Now it is difficult at most medical schools to find cases to demonstrate to the medical students.

Flour, Bread, and Other Cereal Products Enrichment

Malnutrition caused by too little of certain "B vitamins" and iron was widespread 20 years ago but has been greatly reduced in the last ten years through improvement of food products made from grains. The flour, bread, corn meal, cereal breakfast food and macaroni products enrichment program has fortunately brought about substantially increased consumption of the particular nutrients required in order that people not be affected with beri-beri, pellagra and severe nutritional anemia. Starting in 1941, white flour, white bread and farina have been enriched by the addition of amounts of thiamine, niacin, riboflavin and iron, strictly in accord with federal definitions and standards.

Iron deficiency manifests itself in the form of nutritional anemia with weakness, paleness and low resistance as principal symptoms. Those are the four chief types of malnourishment which have been alleviated fully or in part through grain food-products enrichment.

Standards of enrichment for flour and bread, farina, corn and macaroni products are governed by federal regulations under the Food, Drug, and Cosmetic Act. At first, enrichment was adopted by part of the industry on a voluntary basis. During most of the World War II period, all family white flour and all bakery white breads and rolls were required to be enriched under federal War Food Order Number 1. That order was terminated in 1946. At the present time enrichment of flour and bread is voluntary in 22 states; it is mandatory by local law in 26 states and three territories. Some of the 26 states with flour and bread enrichment laws also require enrichment of corn meal and grits. It is difficult to know precisely how much improvement has resulted from the flour and bread and other cereal-products enrichment program. Nevertheless it is the judgment of most of the scientists who have made observations that symptoms of thiamine, riboflavin and niacin shortages are greatly reduced in their incidence during the last ten years. The United States Department of Agriculture [3] has announced that, based on the most careful kind of statistical appraisal, they estimate ten to 25 per cent of the national per capita supplies of thiamine, niacin, riboflavin and iron are derived from the enrichment of cereal food products. These amounts are sufficient to bring marginal individual intakes of those respective nutrients to satisfactory levels, and to lessen the impact of gross deficiencies.

[3] United States Department of Agriculture: *The National Food Situation*, NFS-54, pp. 34-35 October-December (1950).

Only recently a study of dietary habits in Iowa, in the midst of abundant food crops, points favorably to the influence of enriched grain food products. P. C. Jeans, M. D., and others [4] state in part:

> Cereals provided the major part of the daily thiamine intake for each group —and the mean intake for each group was ample . . . . In this state practically all cereal foods and flours are enriched; therefore the intakes of thiamine, iron and riboflavin are all far higher than would be possible with unenriched white flour products. Bread alone supplied from 15 to 31 percent of the thiamine; from 40 to 50 percent was provided by cereal foods. White flour products predominated heavily in the diets, therefore, had the bread and flour been unenriched, the day's thiamine intake would have been cut by 30 to 40 percent and many women would have been close to actual deficiency, if not clinically deficient.

Regarding iron, the authors state:

> . . . cereals provided 30 to 41 percent . . . of the day's iron intake. Had the cereals been unenriched, few women would have ingested as much as 10 mg. of iron daily. These findings demonstrate clearly the worth of the present bread and flour enrichment program, for the dietary habits of the [404] women studied here are probably common in many, if not all, rural and semi-rural areas of the northern section of the country.

Fluorine in Drinking Water for Dental Caries Prevention

The incidence of dental caries, or cavities, in the teeth of children in this country is unfortunately high. Out of a wide diversity of proposals to correct the situation, one fits within the scope of this report —namely the fluoridation of drinking water. For several decades it has been well known that fluorine has an influence on the soundness of structure of dental enamel. Too little fluorine leads to soft enamel. Too much fluorine leads to fluorosis—a discolored or "mottled" enamel. Slight excess of fluorine, even in the levels which produce moderate discoloration, apparently does not in any other way harm the body. In excessively large amounts, fluorine and its salts are highly toxic.

Based on considerable experimentation, it has been found that approximately one part per million of fluorine in the drinking water is very effective in reducing the incidence of dental caries in small children. Caries are reduced as much as 30 to 40 per cent providing fluorine is ingested by them from birth until at least eight years of age. That knowledge has led to the practice of fluoridation of drinking water, which is now being followed on a municipal basis in some 60 cities in this country, of which more than 40 are in the State of Wisconsin.

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[4] Jeans, P. C., Smith, Mary B., and Stearns, Genevieve: "The Dietary Habits of Pregnant Women of Low Income in a Rural State," *J. Amer. Diet. Assoc.*, 28:27-34 January (1952).

An alternative procedure for treating the teeth with the benefits of fluorine is for properly standardized fluorine solutions to be painted topically on the surface of the teeth by the dentists periodically several times per year.

Many organizations, including the American Medical Association, American Public Health Association, American Dental Association, American Water Works Association, Medical Division of the National Research Council, and local organizations, have given their approval in principle to the fluoridation of drinking water. In each case the scientific and professional organizations have emphasized that the information is still not final or complete, but that in view of the overwhelming benefits observed to this date, the practice may well be considered for adoption. For mass benefits in the near future no other procedure is so promising as the fluoridation of drinking water.

National Research Council Committee Reports

One of the very latest reports, issued only a few weeks ago, is in my judgment one of the best. It is the report of the National Research Council's *Ad Hoc* Committee on Fluoridation of Water Supplies.[5] Kenneth F. Maxcy, M.D., The Johns Hopkins University, served as chairman of the committee and had associated with him eight other experts representing the various phases of the fluoridation subject. The committee concluded:

> In view of these considerations, your Committee recommends that any community which includes a child population of sufficient size, and which obtains its water supply from sources which are free from or are extremely low in flourides, should consider the practicability and economic feasibility of adjusting the concentration to optimal levels. This adjustment should be in accord with climatic factors and a constant chemical control should be maintained. With proper safeguards, this procedure appears to be harmless. However, it should be conducted under expert dental and engineering supervision by the state board of health. It should not be undertaken unless this can be provided. How much reduction in the prevalence of caries will actually be realized in the particular community will vary according to local conditions. The procedure will supplement but not supplant other dental health measures. About one half of the population of this country is living in small villages and rural areas and will not benefit by flouridation of public water supplies. Other provisions for preventing dental caries in this fraction of the population should be continued and developed.

[5] *Ad Hoc* Committee on Fluoridation of Water Supplies, Maxcy, Kenneth F., M.D., Chairman: Report of the Comm. Div. of Med. Sc., National Research Council, Washington, D. C. November 29 (1951).

Calcium Principal Dietary Weakness

Calcium has been and still is a serious shortage in many diets. The Bureau of Human Nutrition and Home Economics of the U. S. Department of Agriculture has recently stated: [6]

> Calcium was the nutrient in which diets of urban families most frequently fell below the National Research Council's recommended dietary allowances. . . . only 6 out of 10 city families had diets providing recommended amounts of calcium.

Several methods are possibilities for effecting an improvement: (1) more milk for those not yet ingesting a reasonable amount of either bottled or evaporated milk and/or (2) invoking of calcium enrichment of flour and bread under the optional clause in the federal regulations governing enriched flour and enriched bread.

Other Factors Sometimes Suggested for Food Fortification

The other major category of substances sometimes mentioned for food fortification are certain amino acids of the type present in marginal quantities in foods from grain products, namely, lysine, methionine, cystine and tryptophan. The manufacturing processes resulting in lowered prices for these amino acids are of immediate interest in both the pharmaceutical and livestock feed areas. Concentrates of individual amino acids may have early application to human diets through special (therapeutic) dietary items. I doubt, however, that it will be practicable to fortify any of the low-cost, general-purpose staple foods in the immediate future.

Summary, Conclusions and Recommendations

Thus, in summary, the improvements in nutritive values of widely used staple foods are approximately as follows:

Endemic goiter has been greatly reduced through the readily controllable production of iodized salt. The voluntary use of iodized rather than plain table salt should be urged by renewed educational campaigns, especially to parents of young children. If that procedure fails to assure that most children will be protected against endemic goiter, then this country, like several other leading nations, may need to reconsider mandatory iodization of all table salt. Committees of competent medical, public health and food technology experts should consider the feasibility of lowering the level of iodization from 100 to 50 parts per million.

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[6] Bur. of Human Nutrition and Home Economics, United States Department of Agriculture, Special Report No. 2, Nutritive Content of City Diets (1950).

Vitamin A fortification of margarine, important especially in the diets of families not eating generously of green vegetables and milk and not able to afford more expensive bread spreads, is an important means of preventing vitamin A deficiencies. The fortification of margarine is practiced to such a complete degree voluntarily by manufacturers that no further steps are needed now.

Vitamin D evaporated milk and vitamin D bottled milk are serving very commendable purposes in almost completely eradicating rickets in children. It is advisable, however, to encourage that a higher percentage of all children, especially rural children, be provided the vitamin D milk rather than plain milk products.

Enriched white flour, enriched white bread and rolls, enriched corn meal and grits, and enriched and restored cereal breakfast foods are making a very substantial improvement in the nutrition of a majority of people in this country. The United States Department of Agriculture states that from 10 to 25 per cent of the total supplies of the nutrients thiamine, niacin, riboflavin and iron are provided in the typical dietary through the enrichment of these grain products.

Fluoridation of drinking water as a means of reducing dental caries in children is a practice which has demonstrated outstanding improvements. Nearly one hundred cities are fluoridating drinking water and many more have the practice under consideration. Fluoridation of drinking water under strict municipal control appears to offer the most immediate hope for substantial lowering of tooth decay.

Finally, I should like to emphasize that each one of these cases must be considered on its own merits. Additional studies and observations will likely point the way for improvements on present practices. Meanwhile the achievement of greatly improved nutritional status can be regarded with widespread pride. Thoughtful and well-informed representatives of industry are *strongly adverse to indiscriminate fortification of foods.* To proceed too quickly in the adoption of new practices, before evidence is sound and certain, is bad; to delay needlessly the application of a safe and constructive nutritional improvement is equally undesirable. I believe that iodized salt; vitamin A fortified margarine; vitamin D milk; enriched flour, bread and other grain products; and fluoridation of drinking water are sound steps to better nutrition and health. They should be maintained regularly and with wide support from all who are interested in human nutrition and human welfare.

[The End]

By F. N. PETERS, Jr.

Legislative Controls on Research

THERE is not sufficient time today to discuss all the effects legislation can have on research, nor even to examine how these would vary with different types of laws. Therefore, this paper will deal primarily with what can happen to food research under a specific kind of legislation which has been proposed.

Presumably, everyone agrees that the public is entitled to the best and purest foods that can be produced; that progress toward better foods can most easily be made along the avenue of research; that the addition of chemicals to foods is not harmful *per se* and, finally, that most food and chemical manufacturers, as well as most members of the Food and Drug Administration, are reasonable, honest and sincerely devoted to serving the public faithfully. When disagreements arise, it is the road to be traveled and not the goal to be reached that is the subject of argument.

It surely will be accepted that the industrial application of research is synonymous with change. To a large extent, industrial research laboratories are seeking changes which will (1) result in improved or entirely new products, (2) gain some competitive advantage, (3) produce lower cost operations, or (4) give a financial return from licensing or sale of patents.

If management's freedom to make changes in its products is destroyed, then its incentive to support research is eliminated.

The output of a research laboratory is the fruit of the combined creative power of its individual staff members. The greatest thrill a research worker experiences is the application of his brain-child to a useful purpose. Nothing destroys his morale faster than failure of management to adopt constructive suggestions presented by the research group. Whenever the individual research man reaches the

nd Development in Foods

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conclusion that management cannot or will not adopt new ideas, his attitude toward his work and his employer will change for the worse.

Legislation has been proposed which would destroy the freedom of management to use its best judgment in adopting research findings. In March, 1951, Representative Miller introduced a bill, H. R. 3257, the principal provisions of which are as follows:

A manufacturer must file an application and obtain permission from the Federal Security Administrator before using any substance designed to alter food in any way if that substance "is not generally recognized . . . as having been adequately tested to show that it is not poisonous or deleterious." The application must be accompanied by a great deal of technical information. It may be denied for several specific reasons, but attention is called to the final basis for rejection. The Administrator may issue a denial if "on the basis of any information before him with respect to such chemical, he has insufficient information to determine whether such additive is safe for use."

An appeal from the ruling of the Administrator may be made to a circuit court, whereupon the Administrator will file a transcript of the record upon which refusal was based. The bill then states: "The finding of the Administrator as to the facts, if supported by substantial evidence, shall be conclusive."

This legislation, if it becomes law, will destroy a manufacturer's freedom to make changes in his products. In the first place, any

change in any food, whether made by addition of a new ingredient or whether produced by a new method of processing would be submitted by the prudent manufacturer to the Federal Security Administrator for approval. It will be said that the intent of H. R. 3257 is to require prior-use approval only if new or untried additives are involved. That may be the intent today, but the prudent man will read the law and reason differently. If his proposed food has a new appearance, flavor, texture or odor, whether because of new ingredients or new processing methods, such food contains chemical additives as defined in this bill. If it is new it certainly is not "generally recognized" as either safe or unsafe. It has not been recognized, period—therefore, the prudent manufacturer will submit every new food product for approval before marketing.

Effect on Research

Thus, the real authority to adopt research discoveries is removed from the manufacturer and transferred to the Federal Security Administrator, an appointee of the President. No clairvoyance is needed to know what such a transfer of authority will do to research. Even if financial support were not withdrawn, the effect of the morale of research men would be no less calamitous. All their ideas, all their efforts would be directed toward what would please the Administrator rather than toward what would be better in their own judgment. The judgment of a single man would be substituted for the free judgments of thousands and tens of thousands of research men throughout the country.

Of course, it might be that the Administrator would scrutinize carefully only applications involving chemicals never used before and would automatically approve everything else. However, what might happen and what will happen may be quite different. A rudimentary knowledge of human behavior will show that the Administrator cannot accept changes easily. Under this bill, the ultimate responsibility for the absolute safety of every new food is placed squarely on the Federal Security Administrator. This responsibility is too great for any individual. Acceptance of a new product means nothing to the Administrator financially; he gains no competitive advantage; he cannot claim the doubtful glory of being the inventor. All he can gain is more responsibility—responsibility for what will happen when any approved food is eaten by any one of 150 million persons. Under such circumstances he will do what any man would

do under similar conditions. He will approach the question of decision with a negative attitude. His degree of negativity will increase in proportion to the breadth of the new discovery. Progress through research and a negative attitude toward change are not compatible.

Patent Aspect

This suggests a corollary point. If an improvement is revolutionary, it is probably patentable. If it is covered by patents little pressure will be put on the Administrator to approve the use of the invention except by its owners. The normal reluctance of the Administrator to assume added responsibilities will be supported by the negative or, at best, the indifferent attitude of those in industry not in position to capitalize on the invention. It is not inconceivable that the price of acceptance might be surrender of patent control. If protection under patents resulting from research is weakened or jeopardized, another incentive for support of research is destroyed.

Suppose a manufacturer develops a change that lowers his costs but, in his opinion, does not affect nutritive qualities. Will the Administrator quickly approve a change if the only benefit is to the manufacturer?

Since it must be admitted the Administrator could prevent change, is not the manufacturer protected from the danger of arbitrary rejection or from a completely negative attitude on the part of the Administrator by his right to appeal to the courts for relief? Unfortunately, the answer is "No." Under H. R. 3257, there is no practical means of obtaining relief from the judgment of the Administrator, even though a court might be convinced that he acted unwisely or capriciously. The decision of the court must be based on findings of fact presented by the Administrator. The exact wording of the bill is: "The finding of the Administrator as to the facts, if supported by substantial evidence, shall be conclusive." A circuit court judge once said: "Give me the right to fix the facts and you may have the right to declare the law." [1] The Supreme Court said: "The findings of the Administrator as to the facts, if based on substantial evidence, are conclusive." [2] Substantial evidence does not mean a preponderance—it does not even mean evidence presented by the most eminent or best-qualified witnesses. In practical experience it means a scintilla or bare thread. Anyone familiar with administrative hearings during the past dozen years can recall cases where the testimony of a single

[1] Judge Curtis L. Waller, 17 *Mississippi Law Journal*, 212-220 (1946).

[2] *Federal Security Administrator v. The Quaker Oats Company*, 318 U. S. 218 (1943).

witness, an employee of the Administrator, was considered as "substantial evidence." Instances are known where "findings of fact" ignored testimony of several qualified industry witnesses and were based instead upon the testimony of a single government employee.

Thus, under H. R. 3257, the Federal Security Administrator has complete control of what research developments can be commercialized and the manufacturer has no practical relief by appeal. This absolute power to control the application of research carries with it the power to destroy industrial research.

But suppose the Administrator does not develop a negative attitude but possesses the superhuman qualities that would allow him to assume ever-increasing responsibilities without the spur of incentives. He still must be assured of the safety of new chemicals in foods, the safety of new processes. Each application must be carefully reviewed. Under any conceivable conditions, this means time—it means delay in the application of research. It may mean loss of a competitive advantage for the manufacturer. The more conscientious, the more devoted the Administrator is to the public interest, the more time he will take to study applications. Give the power to control the rate of change and you have given the power to control the rate of research.

Three-Fold Answer to Critics of Viewpoint

Some may feel that this paper has made the worst possible interpretation of the results stemming from the proposed legislation. There are three answers to this. First, nothing has been predicted which could not happen if H. R. 3257 becomes a law. Second, the alleged need for H. R. 3257 is based on the worst possible interpretation of the acts of the food industry. It is based not on what has happened in the past, but on what could conceivably happen in the future. Third, what may happen to food research under this bill should be considered in the light of what has happened under previously enacted legislation.

Before adoption of the Food, Drug and Cosmetic Act of 1938, Senator Copeland, sometimes called the father of this Act, said in reference to the standard-making provision of one of the predecessor bills: "It should be noted that the operation of this provision will in no way interfere with the marketing of any food which is wholesome, but which does not meet the definition and standard . . . ." [3] Mr. Walter

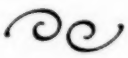
[3] Report No. 361 on S. 5, 74th Cong., Dunn, *Federal Food, Drug, and Cosmetic Act*, p. 246.

G. Campbell, then Chief of the Food and Drug Administration in testimony before a House Committee said, "There can be no objection to the philosophy that any article that is wholesome and has food value and is sold for what it is, without deception, should be permitted the channels of commerce."[4] In spite of these positive assertions, within a few years the sale of farina enriched with vitamin D had been outlawed under the very provision of the act that Senator Copeland said would not produce such a result. There was nothing wrong with the product or its label—it merely did not conform to an arbitrary definition set by the Administrator subsequent to the passage of the Act.

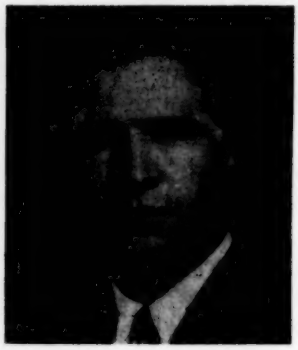
Threat to Research

The introduction of enriched corn meal was delayed for at least two years because of uncertainty as to whether there would be federal standards and, if so, what they would be. A prominent research director told the speaker he would not willingly spend research money on any food for which standards of identity had been promulgated. Another company opposed the suggestion of setting standards of identity for all breakfast foods, for fear that further developments in this field would be prevented. Another large food company delayed an important research project because even if successful, the product in question could not be sold under present definitions. These are specific examples of research curtailed or threatened—not directly from that which was written into an Act in 1938 but because of what the Act came to mean after 1938. Similar administrative interpretations and rules in the future can extend the scope of a law passed today.

This paper neither affirms nor denies the need for further legislation. It does assert that legislation giving the Federal Security Administrator power of life or death over new food products will result in loss of industry-incentives to support research, will decrease the amount of research, will lower the morale of research personnel and will progressively reduce the rate of progress in the food industry in the years to come. **[The End]**



[4] Dunn, work cited, p. 1239.



By MARX LEVA

Comparisons and C
The Miller Bill a

LET ME BRIEFLY RESTATE the principal points of difference between the Miller Bill and the Manufacturing Chemists' Association proposal:

First, the Miller Bill requires affirmative FDA approval in each and every case where a chemical additive is used, in effect making the FDA the guarantor of the safety of a host of products, whereas the MCA proposal leaves the primary responsibility for safety where it now rests, on the chemical manufacturer and the food processor, while at the same time providing that the FDA shall be given advance information on all proposed *new uses* of chemical additives.

Second, the Miller Bill, under its broad definition of the term "chemical additive," applies not only to new and hitherto untested additives, but also to substances that have been in common use for many years—so that FDA could require literally thousands of unnecessary applications on products of long standing to be filed under the Miller Bill. In contrast with this, the MCA proposal would apply existing law to substances already in use—and would apply the *new law* to *new uses*.

Third, the Miller Bill seeks to assign to FDA certain responsibilities which Congress has heretofore vested in the Department of Agriculture. In essence this is an internal jurisdictional matter, involving two agencies of government. The Hoover Commission recommended that the food regulatory functions of the FDA should be transferred to the Department of Agriculture; perhaps in part as a counter-weight to this Hoover Commission recommendation, the Miller Bill would duplicate the functions of the Department of Agriculture by vesting the same type of functions in FDA. While the MCA proposal does not

and Conclusions—
Bill and the MCA Proposal

These Remarks Were Made by the Author, Who Is a Partner in the Law Firm of Fowler, Leva, Hawes & Symington, Washington, D. C., at the Inter-Industry Conference on Chemicals in Foods, Sponsored by the Manufacturing Chemists' Association, Inc.

enter into this jurisdictional issue within the government, it is worthy of note that the Department of Agriculture apparently feels that Congress has provided that department with workable legislation, adequate to enable it to discharge its responsibilities effectively in the pesticide field.

Fourth, the Miller Bill makes it possible for FDA to block technological progress in the food field, by the simple device of administrative delay. Many administrative decisions have been held in abeyance for many months—indeed, in some cases, years—and since the Miller Bill would, in effect, make the FDA the guarantor of safety, there is good reason to fear that administrative delay under the Miller Bill might be the rule rather than the exception. To meet this situation, the MCA proposal provides that 60 days after notification to FDA, the proposed new use may begin.

Fifth, the Miller Bill denies the chemical manufacturer or the food processor the right to appeal to a federal district court when the chemical manufacturer or food processor feels aggrieved over FDA's action or inaction. In lieu of this right of appeal—which the chemical manufacturer and the food processor possess today, under existing law—the Miller Bill provides a right of appeal that is more fictitious than actual. Specifically, the Miller Bill would make the FDA's findings of fact final and conclusive, subject only to an appeal to a circuit court

of appeals which could upset the FDA finding only if, in effect, the court was able to determine that the FDA had acted arbitrarily and capriciously and without any substantial evidence. The MCA approach, on the other hand, would continue to allow the federal district court to determine whether, on the basis of all the evidence, the product should be marketed.

For all of the reasons referred to above, it is the view of MCA that the Miller Bill should not be enacted; and it is also the view of MCA that if there is to be legislation in this field, the proposal we have presented represents a logical augmentation of present law and a constructive approach to a workable solution. As indicated by Mr. Williams, we hope that the discussion at today's symposium will bring forth thoughts and suggestions for improving wherever possible this proposal that we have offered. **[The End]**

• *CLAYTON AND ROBINSON-PATMAN ACTS VIOLATIONS* •

A Federal Trade Commission order prohibiting the use of exclusive-dealing contracts in the leasing of automatic vending machines and in the sale of candy products was affirmed and enforcement granted in the United States Court of Appeals for the Seventh Circuit under date of January 18, 1952. The order was judged not defective for failure to join petitioner's lessees as parties to the proceeding on the ground that the mutuality of the contracts was destroyed and the lessees deprived of valuable contractual rights when the covenants prohibited were inserted for the benefit of the lessor, and were of such a restrictive character that no right of the lessee could be injuriously affected by the order. Petitioner is engaged in developing and leasing automatic vending machines and in purchasing candy, gum, nuts and other confectionery products for distributor resale. The distributors pass them along to the public by means of the vending machines.

The condition that the lessees use only petitioner's candy products is unlawful since the actual effect of this stipulation was to exclude competition from a substantial share of the market as to both lines of petitioner's business. This portion of the order does not interfere with the petitioner's contractual rights in that its provisos furnish ample safeguard for the protection of petitioner's good will and right to compensation.—*Automatic Canteen Company of America v. FTC*, CCH TRADE REGULATION REPORTS ¶ 67,211.

THE PRESENT LAW

By J. PHILIP SMITH

This Address Was Delivered by the Author at the Inter-Industry Conference on Chemicals in Foods, Sponsored by the Manufacturing Chemists' Association, and Held at the Hotel Statler in New York City, January 15, 1952

MY COMMENTS are directed to a brief summary of the present law relating to the use of chemicals in the production of food. The Federal Food, Drug, and Cosmetic Act of 1938 represents what might be termed the cornerstone of existing legislation dealing with the subject.

Before discussing this act, reference should be made to the more recent Federal Insecticide, Fungicide and Rodenticide Act of 1947, as this law relates to the use of pesticides in the vitally important agricultural phase of food production.

No review of present law, no matter how brief, would be complete without directing attention to this legislation. The Federal Insecticide, Fungicide and Rodenticide Act of 1947 requires registration with the Department of Agriculture of all pesticides as defined in the terminology of the Act prior to their delivery into the channels of interstate commerce. Registration involves, among other things, and if requested by the government, a full description of tests made on the product.

Turning to the Federal Food, Drug, and Cosmetic Act of 1938, this legislation, in essence, prohibits the adulteration or misbranding of foods going into the streams of interstate commerce. A food is defined as any article used for food or drink, for man or other animals,

Harris & Ewing

Mr. Smith Is a Member of the Legal Staff of Charles Pfizer & Company, Inc., Washington

chewing gum, and articles used for components of any such article. The following comments are, in the main, directed to the law's prohibitions against the adulteration of foods.

The law defines a food as adulterated if, among other things, it bears or contains any poisonous or deleterious substance which may render the food injurious to health; where the substance is inherent in the food in its natural state, the food would not be deemed adulterated if the quantity of the substance does not ordinarily render the food injurious to health.

If the poisonous or deleterious substance is added to food, the food is automatically deemed adulterated under the law. The only exception to this rule is the case of an added substance which is required in production and by good manufacturing practice, and then only to the extent that the government has established tolerances for the use of this substance in food.

Up until fairly recently, the government had taken a very limited action in setting tolerances, although currently the FDA has given considerable attention to the problem. The Administration has held hearings looking to the establishment of tolerances on chemicals used with certain foods prior to harvest.

A food may also be defined under the law as being adulterated if any valuable constituent has been omitted or extracted from it, or if any substance has been substituted for such constituent, or if damage or inferiority has been concealed in any manner, or if any substance has been added to the food to increase its bulk or weight, or reduce its quality or strength, or make it appear better or have greater value than it is.

Moreover, a food would be considered adulterated if its container is composed in whole or in part of any poisonous or deleterious substance which may render the contents injurious to health.

The law empowers the government to establish standards of identity for all foods, excepting those in a few stated categories. This means that the government, in fixing a standard of identity for food, can prescribe the ingredients required or optional that can be employed by the manufacturer. It might be pointed out that to date standards of identity have been established for a variety of foods ranging alphabetically from canned apricots to certain wheat products.

Any manufacturer who delivers into the channels of interstate commerce a food for which there is a standard of identity, and which contains an ingredient not permitted by the standard or authorized by a temporary permit from the government, is guilty of a violation of the law. Provision is also made in the law for precertification of the government of coal tar dyes which are harmless and suitable for food use.

Under the law, the Food and Drug Administration of the Federal Security Agency is charged with the responsibility of enforcing the FDA Act, just as the Department of Agriculture is charged with the responsibility of enforcing the 1947 Act relating to pesticides.

In dealing with violations of the law, the FDA has recourse to three distinct legal procedures; the action to be taken in any particular instance would depend upon the urgency of the situation and consideration of the various factors relevant to the given case.

The Administration may bring criminal prosecution against any person violating the legal prohibitions against food adulteration. A violation constitutes a misdemeanor punishable by a maximum of one year in prison and/or a fine of up to $1,000. The penalty is increased for repeated violations up to a maximum of three years' imprisonment and/or up to $10,000 in fines.

The Administration might also take court action directed to the seizure of an adulterated food going into or in the channels of interstate commerce. The law also provides the Administration with the right of recourse to the courts for the issuance of injunctions preventing adulterated foods from reaching the consuming public.

Under the Food, Drug, and Cosmetic Act, it is the manufacturer's responsibility to assure that a food meets the standards set up in the law. An intimate and thorough knowledge for compliance with such

law is therefore quite obviously a prerequisite to the fulfillment of the manufacturers' legal obligations. For example, a manufacturer's compliance with the Federal Food, Drug, and Cosmetic Act assures that no new chemical will be utilized in the food offered the public by such manufacturer prior to adequate toxicological testing to demonstrate the safety of the chemical for the proposed use.

In concluding, it might be observed that the quality of this nation's food supply and the continuing advances in the important field of nutrition bear ample evidence that industry, by and large, working in cooperation with both the Food and Drug Administration, and the Department of Agriculture, is admirably fulfilling its responsibility to the consuming public. **[The End]**

• GOODRICH SUCCEEDS WILLIS •

On February 13, Federal Security Administrator Oscar R. Ewing announced the appointment of William W. Goodrich as Assistant General Counsel of the Federal Security Agency and Chief of the Food and Drug Division, General Counsel's Office, to succeed Daniel P. Willis.

Mr. Willis retired after having been an attorney in the government service since 1930 and with the food and drug program since 1935. He had been assistant general counsel since 1945. Administrator Ewing said of Mr. Willis:

"He has been a loyal and devoted career employee giving legal guidance on this program through many years and has helped materially in its development."

Mr. Goodrich, since his return from military leave (1942-1945), prepared the briefs and argued the *Kordel* case in the United States Court of Appeals for the Seventh Circuit; tried the *Urbuteit* case; and assisted in drafting the Miller Amendment to the Food, Drug, and Cosmetic Act, clarifying interstate jurisdiction, and the Durham-Humphrey Amendment of last year, which strengthened federal controls over prescription drugs. He first entered government service in 1939.

Both Daniel P. Willis and William W. Goodrich are well known to the readers of the JOURNAL, since they have been regular contributors of articles—both separately and in collaboration—since the magazine's inception.

The Present Law and Proposed Changes

By G. J. WILLIAMS

This Is the Author's Talk Before the Inter-Industry Conference on Chemicals in Foods, Sponsored by the Manufacturing Chemists' Association, Inc., January 15, 1952. Mr. Williams Is a Member of the Legal Staff of The Dow Chemical Company

YOU HAVE HEARD others summarize the existing Federal Food, Drug, and Cosmetic Act and the new Miller Bill. I have been given the opportunity to present the Manufacturing Chemists' Association's approach to changes in the present law.

First, we believe that the present laws relating to pesticides are effective and adequate to protect the American public, and we would not propose any change in the laws relating to these products. My further remarks will not apply to any substance, chemical additive or what you will, subject to the Federal Insecticide, Fungicide or Rodenticide Act.

Second, we believe that the present legislation vests the government with adequate authority over the use of chemicals in foods. As Mr. Smith has pointed out, it is unlawful to ship in interstate commerce any food bearing or containing an added poisonous or deleterious substance. *If this law is enforced, there can be no danger to the public health through the use of chemical additives.*

Third, the one area in which the present legislation may need strengthening is in assuring that the Food and Drug Administration is given advance notice of proposed new uses of chemical additives. Today, and we must admit this possibility, a chemical additive can be put to a new use and such use can continue for some time without the Food and Drug Administration knowing anything about it. Enforcement is difficult when you are working under such a handicap as lack of knowledge of violations.

With these facts in mind, the Manufacturing Chemists' Association recommends that consideration be given to incorporating in the present law a provision prohibiting any new use of any chemical additive in or on any food until 60 days after notice of such intended use has been filed with the Food and Drug Administration. This notice could be filed by either the manufacturer of the chemical additive or a food processor and should include these things:

(1) Applicable pharmacological and toxicological data available.
(2) The known composition of the chemical additive.
(3) An analytical method for determining residues.
(4) Directions for use of the chemical additive with respect to the specific food or foods and the specific use or uses proposed.
(5) A sample of the chemical additive.

In addition we would propose that provision be made for conferences between the Food and Drug Administration and the person filing the notice so that the intended use could be further discussed.

We would not propose that the Food and Drug Administration be given *the power to deny or the responsibility of* approving such use by an administrative decision. We do not favor prior approval or precertification.

If the Food and Drug Administration, after reviewing the submitted data feels that the intended use should be denied because it presents a hazard to the public health, it may proceed under the existing enforcement powers of seizure, injunction or criminal proceedings as outlined by Mr. Smith.

Printed copies of our approach are available and we invite your study, comments and criticism.

Practical Application

How would this legislation work as a practical matter? Suppose a food processor wants to use a chemical additive in canned beets, asparagus and peas. Either the food processor or the manufacturer of the chemical additive would file a notice of the proposed use with the Food and Drug Administration, giving the data and other information required. Very probably, the manufacturer of the chemical would furnish the toxicological data, the known composition of the chemical additive and an analytical method. The food processor might furnish

(Continued on page 160)

Administrative Progress

OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT IN 1951

By GEORGE P. LARRICK

This Address Was Delivered at the Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association, New York City, January 23, 1952

Civil Defense

ONE NEW DEVELOPMENT during the year involved preliminary preparations for the Food and Drug Administration to fulfill its obligation in the event of an atomic, biological or chemical attack upon the United States. During the spring of 1951, all professional field employees and many of the Washington employees were given an intensive one-week's training in civil defense from the standpoint of our food, drug and cosmetic supplies. This course was presented in 17 of the major cities throughout the country. It was attended not only by federal food and drug inspectors and chemists but also by key state and local food and drug officials. Thus, in the aggregate, the course was attended by about a thousand officials.

Each course covered the fundamentals of atomic, biological and chemical warfare and considered methods of protecting the inspecting personnel, as well as the food and drug supplies, in case of enemy action against this country. The information included in the course had been prepared in collaboration with the federal Civil Defense Administration, the Atomic Energy Commission, the Department of Defense, the Public Health Service and the Department of Agriculture.

In addition to teaching the methods of using the technical equipment necessary to measure atomic, biological or chemical contamination of our food and drug supplies, each of our 16 field districts prepared, in cooperation with state and local civil-defense officials and cooperating health agencies, a plan for the participation of each in

The Author Is Deputy Commissioner, Food and Drug Administration, Federal Security Agency

civil defense. Thus, a broad plan has been devised to deal with the problem if it should ever arise. A rapid method for detecting contamination of foods and drugs with radioactive fission products has been distributed to each field office, together with standards to be used in separating seriously contaminated material from that which is suitable for immediate consumption. Further research and training are needed and will be undertaken.

Kansas City Flood

A catastrophe occurred last summer which permitted an evaluation of that part of our civil-defense plan which involves the immediate marshaling of state, city and federal food and drug enforcement people to deal as a team with contaminated foods, drugs and cosmetics.

On July 13, 1951, flood waters from the Kaw River submerged the Kansas City central industrial district. Previously, cities and towns above Kansas City had been inundated. When floods inundate cities, the sewer systems work in reverse. As the flood waters rise above the outlets of the sewers, filth is forced backward through the mains and into the areas flooded.

Before the flood waters receded, surveys were made to determine the extent of the problem. Beginning the week of July 15, it was possible to gain access to many of the flooded areas and, based on the preliminary surveys, plans were made to control distribution of flood-contaminated products.

The first problem was to gain control of contaminated foods and drugs. Embargoes were placed by state and city agencies on all foods and drugs which had been touched by contaminated flood waters. Simultaneously, provisions were made for release of these materials

to the owners when it had been determined what could properly be done with the damaged products. No effort was made to effect federal seizures.

The team of city, state and federal inspectors divided the assignment. For example, in the State of Kansas, in towns and communities upstream, the work was handled by Kansas State authorities with the assistance of two federal men. In the State of Missouri, down the Missouri River from Kansas City, our men worked with their counterparts in the Missouri State organizations. In the Kansas City, Kansas, and Kansas City, Missouri areas where it was estimated that total damage from the flood approached the billion-dollar mark, in addition to the team of Kansas City district, city, and state inspectors, food and drug personnel were temporarily transferred from various parts of the country. From the food and drug standpoint, the great bulk of the Kansas City problem was in a rather limited geographical area and included, first, the industrial section, second, the railroad yards and, third, the mills and elevators. Planning conferences were held between the regulatory officials and representatives of various segments of the industry. One conference was held with representatives of chain stores whose warehouses had been flooded. Another was held with claim agents of the various railroads. With the Kansas City Board of Trade we worked out a plan for handling damaged wheat and other grains in possession of common carriers, mills and elevators.

Every assistance was given to those who suffered from the catastrophe so that they could recover as much salvage as possible. The primary guide, however, was the interest of the consumer. The program worked smoothly. Products in water-tight containers were released. In the case of many perishable products, salvage was not possible because they had been too long without refrigeration. Their destruction presented a special problem, since there were not enongh dumps available to take care of this material. New sanitary landfills were developed, and one of the functions of the inspectors was to provide information as to where all manner of decomposed foods could be dumped.

The problem with the railroads was a tremendous one. More than 3,600 railroad cars were involved. Some 40 per cent of these contained food. One of our inspectors was assigned to each of the railroads. These men worked with the railroad crews as the rails and other services were restored. Where records were still available, the cars containing products subject to the Food, Drug, and Cosmetic Act were segregated.

Most of the salvage and destruction was carried out in Kansas City, but because of the congestion in that area special arrangements were made to permit cars to proceed to destination, where the salvage would be conducted under appropriate supervision.

We take considerable pride in the fact that in spite of the many possibilities for friction and the chaos that existed, there were practically no cases of serious differences between the industries involved and the several enforcement groups participating in the program.

Economic Cheats

The past year has been marked by an increase in the number of violations involving substantial economic cheats. This is a sign of the times, and always occurs as prices rise. More than 100 cases brought because of the addition of about 25 per cent water to oysters is an example.

Food Faddists

Another development has been the increased attention given to food faddists who seek to cash in on the false philosophy that our soils are impoverished and incapable of growing nutritious foods and that our staple foods are debased and made non-nutritious by modern manufacturing procedures. Adequate regulation in this field presents troublesome current problems.

Illegal Sale of Dangerous Drugs

The sale of dangerous drugs without prescription is being given increasing attention. The courts are aware of the seriousness of this problem and, particularly in the case of the habit-forming drugs, have substantially increased the penalties imposed.

As the difficulty of buying drugs such as the barbiturates without prescription increases, we see more and more evidence that the illicit traffic in these commodities is going underground. This trend increased the difficulty of enforcement and in many instances places the investigators in personal jeopardy.

Wheat and Flour

Probably the largest investigational program ever conducted by the Food and Drug Administration was completed during the past year. This involved a nationwide study of wheat and flour. This investigation would not have been possible without the cooperation of

the milling industry and the grain trade. The primary purposes of the study were (1) to determine the relationship of insect infestation in wheat to the insect fragment count in the flour made from it; (2) to evaluate the effectiveness of mill cleaning equipment and procedures in dealing with infestation and contamination of wheat; and (3) to determine the incidence and level of insect infestation in commercial wheat as received at representative flour mills over a 12-month period. The study dealt with both surface infestation and internal infestation.

The report of the investigation is to appear in the February issue of the *Journal of the Association of Official Agricultural Chemists.* Preprints have been distributed. Conclusions to be drawn from this study show unmistakably that a big problem does exist in this important industry. Large quantities of grain are being attacked by rodents and insects. Presently available cleaning equipment cannot be depended upon to completely remove this extraneous material. We are continuing our cooperation with the milling industry and with the grain trade and are currently discussing with them the steps which they and we will take looking toward the solution of this problem.

Durham-Humphrey Bill

In speaking of the legislative progress of the Food, Drug, and Cosmetic Act in 1951, perhaps the Durham-Humphrey amendment should be mentioned, at least briefly. There are some in this audience who have already given attention to this amendment and perhaps an extended discussion of it is unnecessary. The bill in the form in which it finally passed, after some disagreements among some of us, does provide for the regulation of drugs which should be sold only for use under the supervision of a physician or other practitioners licensed by law to administer them.

We have sought in the preparation of proposed regulations under this amendment to facilitate compliance with its requirements. We are convinced that for the orderly enforcement of the statute, an advisory list of drugs which can legally be sold only upon prescription should be available. We have invited the cooperation of the drug industries in the preparation of such a list.

Delaney Committee

As you know, the Select Committee of the House of Representatives under the chairmanship of Congressman Delaney has continued

its investigation of the broad subject of the introduction into foods of substances whose safety is not established. These hearings have brought forth a variety of suggestions for the solution of the problem. The last development was the passage of a resolution empowering this committee to investigate cosmetics, as well as foods. We understand that the committee has or will shortly conclude the hearings. Like yourselves, we will anxiously await their report.

Barbiturates

During the year a subcommittee of the Committee on Ways and Means of the House of Representatives, in connection with their consideration of narcotics, held hearings on the Rogers Bill dealing with barbiturates. Representatives of the United States Public Health Service, the Narcotic Bureau and ourselves, among others, were called to testify before this committee.

Following the hearings of the Boggs Subcommittee, the committee addressed a letter to the Federal Security Administrator asking him to consult with the Narcotic Bureau, the Treasury Department and the Department of Justice and, on the basis of such consultation, to make a recommendation to the committee as to the form of legislation most desirable. We obtained from the Narcotic Bureau and the Treasury Department a statement which expressed the policy that they do not wish to be named as the enforcement agency in tax laws which do not raise important sums of money but which are primarily for the purpose of the regulation of social problems. We received from the Justice Department an opinion that from a constitutional standpoint, legislation in this field under the commerce clause would be as valid as under the taxing power. In transmitting these views to the Boggs Committee we have expressed the opinion that at least a trial should be made of legislation less severe than the Harrison Anti-Narcotic Act. Instead, we have suggested that the possession of barbiturates for nonmedical use be defined as a federal crime. In other words, the purpose of the legislation would be to place no bars for the legitimate manufacture and distribution of barbiturates when they are used under the supervision of physicians but to outlaw sale or possession for nonmedical use.

Our proposal includes a declaration of a Congressional finding that intrastate traffic in barbiturates for nonmedical purposes constitutes a burden on legitimate interstate industry and should likewise be regulated.

The most recent developments in this area involve communications and conversations with members of both the House and the Senate who are becoming impatient and who themselves are considering the introduction of bills.

If our personal wishes were to be guiding, we would hesitate to assume responsibility for more extensive regulation of the barbiturates. It will not only be a difficult job, but it takes our inspectors into areas where we have not extensively operated in the past. Bootlegging, crime and all manner of unpleasant occurrences inevitably will be associated with these drugs which are sought for nonmedical uses. Recently, one of our inspectors had his skull cracked with a blackjack and another was held at gunpoint for two hours during the course of the investigation of barbiturate sales.

In spite of these unpleasant realities, we are convinced that some legislation dealing with the barbiturates is necessary in the public interest. We feel that we must do what we properly can to secure adequate control of habit-forming drugs and if the Congress decides that the assignment of enforcement should be made to the Food and Drug Administration, we will then undertake that job.

Recodification of Federal Food, Drug, and Cosmetic Act

H. R. 3758 is a bill to revise, codify and enact into law Title 21 of the United States Code, entitled "Food and Drugs." We have had the opportunity to review the proposed recodification of the food and drug law, and our understanding is that the codification will make no substantial change in the statute. Accordingly, we have endorsed this bill and, as far as we know, there is no obstacle to its passage.

Various other legislation is pending some of which will no doubt be the subject of hearings during the Eighty-second Congress, Second Session.

Reappraisal of Practices

One development during the year which is a matter of concern to everyone in government was the disclosure that some public officials have not conducted themselves with that degree of decorum calculated to provide complete assurance to the public of the propriety of their actions.

Quite naturally, as the result of these revelations we indulged in considerable introspection and took a fresh look at our practices throughout the country. We found ourselves substantially reassured

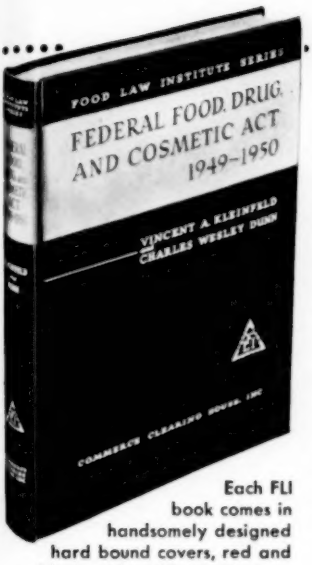
when we overhead a conversation between a young lady of about 19, who is a member of our clerical staff, and another woman of more advanced years in the same office who takes a quite strict motherly interest in the deportment of youngsters on the staff.

The young lady had been regaling some of her associates with an account of the fun which she had had over the weekend. She offended the matron's conception of the proprieties when she reported that she had enjoyed two highballs and had not reached home until 3:00 a. m. The older woman interrupted the girl's recitation with the question, "Young lady, if you behave like that what do you expect to say to St. Peter when you arrive at the Pearly Gates?" Whereupon the girl replied, "I will just tell St. Peter that I worked for the Pure Food and Drug Administration." **[The End]**

THE PRESENT LAW AND PROPOSED CHANGES—
Continued from page 152

the directions for use. Thus, the notice would be a combined effort. Sixty days after filing such notice, any food processor would be free to go ahead with the proposed use without any further action by the Food and Drug Administration. Any other use of the chemical additive or any deviation from the use as proposed would be a violation of the law unless a supplementary notice was filed.

We are convinced that this program of legislation is sound. It protects the public in that no food can be shipped in interstate commerce if it bears or contains any added poisonous or deleterious substance. It is sufficiently flexible to allow for new discoveries and developments. It assists the Food and Drug Administration in that it will have an opportunity of reviewing, in advance, each and every proposed new use of a chemical additive—yet, it avoids the many disadvantages of administrative finality and leaves to the *courts* the decision as to whether or not the law has been violated. *This is the truly American way of doing things.* **[The End]**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The Food Law Institute, Inc., was organized by a number of leading food manufacturers in 1949, and is principally supported by them. A public organization, the Institute was established for constructive development of the food law, including the associated drug and cosmetic laws. It is ably headed by Charles Wesley Dunn, a foremost authority on food, drug, and cosmetic law.

One of the major objectives of the Institute is to prepare basic research compilations of the food law. This will provide for everyone concerned with the law an adequate library of authoritative reference books on it. These books will be written by outstanding authorities in the field and will be published by Commerce Clearing House, Inc., leading publisher of Topical Law Reports and publications on federal food and drug law. The series of books will be known as the FOOD LAW INSTITUTE SERIES.

These Three Books Are Already Available:

- Federal Food, Drug, and Cosmetic Act, Judicial and Administrative Record —1938-1949, *by Vincent A. Kleinfeld and Charles Wesley Dunn.*
- Federal Food, Drug, and Cosmetic Act, Judicial and Administrative Record —1949-1950, *by Vincent A. Kleinfeld and Charles Wesley Dunn.*
- Federal Food, Drug and Cosmetic Law, Administrative Reports—1907-1949. Introduction *by Paul B. Dunbar;* Foreword *by Charles Wesley Dunn.*

Projected Books in This Series Will Cover Such Subjects as:

● general state food, drug, and cosmetic laws ● food, drug, and cosmetic laws of the British Commonwealth ● modern nutrition law developed outside the food law ● federal and state action on the addition of chemicals ● a bibliography of the food, drug, and cosmetic law ● food products liability law ● others to come.

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